Dexcom G5™ mobile

CONTINUOUS GLUCOSE MONITORING SYSTEM

User Guide

IMPORTANT CONTACTS AND NUMBERS

Emergency Phone Number: _____

Your Healthcare Professional: _____

Your Receiver Serial Number: _____

Your Transmitter Serial Number: _____

_____

Dexcom® Technical Support/Patient Care Team: **1.877.339.2664**

Dexcom Website: dexcom.com

Nearest Hospital: _____

_____

Dexcom®

Table of Contents

Part 1: Getting Started

Glossary 5

Chapter 1 - Beginning Your Dexcom G5™ Mobile Continuous Glucose Monitoring (CGM) System Journey 9
1.1 Introduction 9
1.2 Self-Paced Resources 10
1.3 Your Dexcom Account 12

Chapter 2 - Indications for Use and Safety Statement 15
2.1 Introduction 15
2.2 Important User Information 15
2.3 Safety Statements 16
2.4 Overview of Safety Statements 17
2.5 General CGM System Warnings 20
2.6 Calibration Warning and Precautions 20
2.7 System/Hardware/Software Warnings and Precautions 22

Chapter 3 - Risks and Benefits 29
3.1 Risks 29
3.2 Benefits 30

Part 2: Let's G5™! The Basics

Chapter 4 - What Is the Dexcom G5 Mobile CGM System? 35
4.1 System Description 35
4.2 Safety Statement 35
4.3 The Dexcom G5 Mobile CGM System 36
4.4 What's New to the Dexcom G5 Mobile CGM System? 38
4.5 System Information 38
4.6 System Components 39
4.7 Smart Device Overview 47

Chapter 5 - Set up Your Display Devices 49
5.1 Introduction 49
5.2 Safety Statement 49
5.3 Why Different Monitoring Methods? 50
5.4 Dexcom G5 Mobile App 50
5.5 Dexcom G5 Mobile Receiver 63

Chapter 6 - Starting a Sensor Session: Inserting Sensor, Transmitter, and Starting Your Session 69
6.1 Overview 69
6.2 Safety Statements 70
6.3 Prepping for Sensor Insertion 72
6.4 Choosing Your Insertion Site 75
6.5 Inserting Your Sensor 76
6.6 Attaching Your Transmitter 80
6.7 Loose Sensor Pod 81
6.8 Starting Your Sensor Session 82
6.9 Receiver *Bluetooth*® Tips 86
6.10 Sensor Session Warmup 90

Chapter 7 - Calibration 91
7.1 Introduction 91
7.2 Calibration Overview 92
7.3 Safety Statements 93
7.4 When to Calibrate 95
7.5 Calibration Prompts 96
7.6 Preparing for Calibration 100
7.7 Ready? Set? Calibrate! 100
7.8 Calibration Errors 106

Chapter 8 - Ending Your Sensor Session and Transmitter Session 109
8.1 Introduction 109
8.2 Safety Statements 110
8.3 Ending Your Sensor Session 110
8.4 Remove Sensor Pod and Transmitter 124
8.5 End of Transmitter Battery 126

Part 3: Next Steps - Getting the Most out of Your Dexcom® CGM

Chapter 9 - Home Screen, Rate of Change Arrows, and Errors 133

9.1 Introduction to Home Screens 133
9.2 Safety Statements 133
9.3 Overview of Home Screen 134
9.4 Rate of Change Arrows 145
9.5 Error Messages 146

Chapter 10 - Daily Events Affect Your Glucose Trends and Patterns 153
10.1 Introduction 153
10.2 What Is an Event? 153
10.3 Entering Events 162
10.4 Viewing Events 170

Chapter 11 - Sensor Glucose Alarm and Alerts 173
11.1 Introduction 173
11.2 Safety Statements 174
11.3 Alarm and Alerts 175
11.4 Alarm and Alerts Screens 177
11.5 App: Alarm/Alert Recommended Settings 183
11.6 Receiver: Default Beeps and Vibrations 184
11.7 Clearing Alarm/Alerts 188

Chapter 12 - On the Go With G5: Customizing Your Alarm and Alerts 191
12.1 Introduction 191
12.2 Safety Statement 192
12.3 Changing App Alarm and Alerts 192
12.4 Changing Receiver Alarm and Alerts .. 204

Part 4: Everything Else G5

Chapter 13 - Warranty: The Fine Print 215
13.1 Introduction 215
13.2 Receiver Warranty Information 215
13.3 Transmitter Warranty Information 217
13.4 Dexcom's Obligations Under the Limited Warranty 219

Chapter 14 - How to Take Care of Your Dexcom G5 Mobile CGM System 221
14.1 Introduction 221
14.2 Basic Maintenance 222
14.3 Storage 226
14.4 Checking App and Receiver Information 227
14.5 System Disposal 228

Chapter 15 - On the Go With Dexcom G5 Mobile CGM System: Getting Through Security 229
15.1 Introduction 229
15.2 Going Through Security 229

Chapter 16 - Need Help? You're Not Alone! 233
16.1 Dexcom Technical Support 233
16.2 Patient Care Team 234
16.3 Sales Support Team 235
16.4 Corporate 235

Chapter 17 - Technical Information 237
17.1 Device Performance Characteristics .. 237
17.2 Product Specifications 275
17.3 FCC Requirements 283

Chapter 18 - Troubleshooting 285
18.1 Introduction 285
18.2 Safety Statements 285
18.3 Troubleshooting 287

Chapter 19 - Symbols on Package Labels 299

Part 5: Sharing Is Caring

Chapter 20 - Dexcom Share™ 303
20.1 Learning About Dexcom Share 303
20.2 Dexcom Share Overview 307
20.3 Risks and Benefits 309
20.4 Safety Statement 310
20.5 Setting up Dexcom Share 313
20.6 Using Dexcom Share 323
20.7 Dexcom Follow™ App 328
20.8 Troubleshooting 330

Index 333

1

GETTING STARTED

- Glossary
- Getting Started
- Indications for Use and Safety Statement
- Risks and Benefits

Page intentionally left blank

Glossary

A1C	Blood test used to diagnose type 1 or 2 diabetes and to gauge how well you're managing your diabetes. The A1C test result reflects your average blood sugar level for the past two to three months.
Alternative Site Testing	Using a blood sample from non-fingertip (alternate) sites such as the palm, forearm or upper arm for meter readings. Do not use alternative site testing to calibrate the Dexcom G5™ Mobile CGM System, only use fingerstick measurement.
App	A self-contained program or piece of software designed to fulfill a particular purpose; an application, especially as downloaded by a user to a smart or mobile device. The Dexcom G5 Mobile App was developed as a display for continuous glucose monitoring.
Blood Glucose (BG) Value	BG is an abbreviation of blood glucose. Blood glucose value is the amount of glucose in the blood measured by a BG meter.
Blood Glucose Meter/Meter/BG Meter	A blood glucose meter is a medical device used to measure how much glucose is in the blood.
Calibration	Calibration is a comparison or measurement between your meter's fingerstick BG values, and the sensor's interstitial fluid glucose readings. Although blood and interstitial fluids are similar, glucose concentration is higher in your blood. Calibration allows alignment between your sensor and meter readings. When you calibrate, you take a fingerstick measurement from your meter then enter the value into your receiver or smart device. The system uses that value to verify the sensor glucose reading is on track.

(Continued on next page)

(Continued from previous page)

Continuous Glucose Monitoring (CGM)	Continuous glucose monitoring (CGM) systems use a sensor inserted under the skin to check glucose levels in interstitial fluid. A transmitter sends sensor glucose readings to a display device. Users must confirm glucose levels with a BG meter before making a change in treatment.
Contraindication	A safety statement outlining specific situations where the Dexcom G5 Mobile should not be used because it may be harmful to you. The risk of use clearly outweighs any possible benefit.
Hyperglycemia	High blood glucose. Same as “high” or high blood sugar. Hyperglycemia is a characterized by an excess of glucose in the bloodstream. It’s important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications. The default high alert in the Dexcom G5 Mobile CGM System is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemic setting for you.
Hypoglycemia	Low blood glucose. Same as “low” or low blood sugar. Hypoglycemia is characterized by a low level of glucose in the bloodstream. It’s important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications. The default low alert in the Dexcom G5 Mobile CGM System is set to 80 mg/dL. Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.
Indications	A condition making a particular treatment or procedure advisable. How, for what purposes, and under what circumstances you should use the Dexcom G5 Mobile CGM System. Indications let you know who should use the Dexcom G5 Mobile CGM System and when.

(Continued on next page)

(Continued from previous page)

IP	The International Electrotechnical Commission (IEC) is a nonprofit, non-governmental, international organization created to produce safety standards for electronics. One of the safety standards it designed is the Ingress Protection (IP) Marking which classifies and rates how protected an electronic device is against dust, water, accidental contact, etc. IP ratings are numerical, with the number based on the conditions the electronic device comes across. An IP22 rating lets you know your electronic device won't allow you to stick your fingers in it and won't get damaged or be unsafe during specific testing with water dripping down.
Jailbroken	The removal of limitations and security measures set by the manufacturer on a smart device. The removal poses a security risk and data may become vulnerable. Do not use, install or run the Dexcom G5 Mobile App on a jailbroken smart device. The app may not work correctly on a jailbroken smart device.
Landscape	If your smart device is oriented sideways.
mg/dL	Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.
Portrait	If your smart device is oriented vertically.
Precaution	A safety statement regarding any special care to be exercised by you or your healthcare professional for the safe and effective use of the Dexcom G5 Mobile CGM System.
RF	Radio-frequency transmission used to send glucose information from the transmitter to the receiver or smart device.
Safety Statement	A statement of the intended uses of Dexcom G5 Mobile CGM System and relevant warnings, precautions, and contraindications.

(Continued on next page)

(Continued from previous page)

Sensor Session	The seven day monitoring period after inserting a new sensor. During this time frame, your glucose is being monitored and reported every five minutes, with data being sent to your display device(s).
Smart/Mobile Device	A smart/mobile device is an electronic device that is cordless (unless charging), mobile (easily transportable), connected (via Wi-Fi, 3G, 4G, etc.) that can operate to some extent autonomously. Examples of smart/mobile devices are smartphones, tablets, or phablets.
Warning	A safety statement letting you know the following feature has important hazard information. Describes serious and life threatening circumstances of using the Dexcom G5 Mobile CGM System, their consequences, and how to avoid the hazard.

Chapter 1

Getting Started:

Beginning Your Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System Journey

1.1 Introduction

Welcome to the Dexcom G5 Mobile family!

We are excited you chose us to partner with you in your journey to manage your diabetes. As a continuous glucose monitoring (CGM) device, the Dexcom G5 Mobile CGM System allows you to break free from constant fingersticks. But how do you use the Dexcom G5 Mobile CGM System? What are its features? Do you need to avoid anything?

Where do you even begin?

This chapter is the first step to answering these and many other questions.

After this chapter, you will be able to:

- Describe different training resources
- Locate tutorials about using the Dexcom G5 Mobile CGM System in your diabetes management
- Find Dexcom G5 Mobile System's step-by-step instructions
- Recall how to use the User Guide
- Explain why you need a Dexcom® account

We have numerous resources available to help you to get the most out of your Dexcom G5 Mobile CGM System. Between our self-paced training resources and our friendly and knowledgeable Dexcom customer support teams, help is always available.

First Things First - Learning How to Learn

Knowing about the Dexcom G5 Mobile CGM System is your first step in creating a successful CGM experience. Before using it, learn about it.

You have numerous self-paced resources, helping you get to know the Dexcom G5 Mobile CGM System:

1. Tutorials
2. Quick Start Guide
3. User Guide

No matter which resource you select, make sure you review them prior to using your new CGM system.

1.2 Self-Paced Resources

Tutorials

Along with step-by-step instructions, our tutorials illustrate how real-time CGM can assist in your daily diabetes management. The following is a list of tutorials and how to access them.

Online Tutorials

First Steps With Your Dexcom CGM
Designed for those who have never used a Dexcom CGM. This tutorial covers what to expect in your first week and includes links to step-by-step videos on how to insert your sensor, calibrations, ending a sensor session, etc.

Next Steps With Your Dexcom CGM
Just finished First Steps or already familiar with how a CGM can benefit you? This tutorial covers looking at trends and introduces some advanced features including our reporting tools.

Accessing Online Tutorials:

From dexcom.com homepage, **click** *Support*, **click** *Training*.

Once you have viewed the online tutorials you should be pretty comfortable with what CGMs do and how the Dexcom G5 Mobile CGM System can help you.

Offline Tutorials

You don't need to be tied to the Internet to view our instructional tutorials, they're also available offline.

Accessing Offline Tutorials:

- USB Card
  - In the receiver package

Written Mobile Resources

Quick Start Guide (QSG)

The Dexcom G5 Mobile Quick Start Guide compliments the tutorials by proving the same step-by-step instructions in a booklet form or within the app.

One of the great things about the QSG is you can use it in conjunction with the videos, taking notes as you go!

Accessing the QSG:

- Receiver package
  - Booklet

Both the tutorial and the QSG give you brief look at the Dexcom G5 Mobile CGM System. But what if you want more detailed information?

User Guide

Your Dexcom G5 Mobile CGM System reference book!

This user guide gives you the most extensive overview of the system detailing features, important safety information and so much more.

To download an ebook of the user guide or request a printed user guide, visit dexcom.com/guides.

The Dexcom G5 Mobile User Guide is grouped into six separate parts:

Part 1: *Getting Started*

1. Glossary
2. Getting Started
   a. Learning how to learn about the Dexcom G5 Mobile CGM System
   b. Registering at dexcom.com
3. Indications for Use and Safety Statement
4. Risks and Benefits

Part 2: *Let's G5! The Basics*

1. Introduction to the Dexcom G5 Mobile CGM System
2. Choose and Set up Your Display Device(s)
3. Initiating a Sensor Session: Inserting the Sensor & Transmitter
4. Calibration
5. End a Sensor Session

Part 3: *Next Steps - Getting the Most out of Your Dexcom G5 Mobile CGM System*
Once you are up and running, how you can maximize the Dexcom G5 Mobile features:

1. Reading Trend Graph Screens and Recognizing Trends
2. Events
3. Alarm and Alerts
4. Sounds for Alarm, Alerts and System Messages

Part 4: *You Take Care of Your G5, and It Takes Care of You!*

1. Warranty
2. Dexcom G5 Mobile CGM System Maintenance
3. Travel Tips
4. Customer Service Contacts
5. Technical Information
6. Troubleshooting
7. Package Label and Product Symbols

At the end of your Dexcom G5 Mobile System User Guide, Part 5, is the user guide of a new Dexcom G5 Mobile System feature: Dexcom Share™.

Part 5: *Sharing is Caring*

1. Dexcom Share
    a. What Is Dexcom Share?
    b. Setting Up Dexcom Share
    c. How to Use Dexcom Share
    d. Your Followers
    e. Troubleshooting

Part 6

1. Index for Dexcom G5 Mobile System and Dexcom Share

How to Use Your User Guide

All chapters in the Dexcom G5 Mobile User Guide are laid out the same way:

The beginning of each chapter lists what you'll be able to do after you have finished, after that, any applicable safety statements you need to know, followed by the chapter's content. At the end, there's a recap of what was covered and what's in the next chapter.

1.3 Your Dexcom Account

You'll need a username and password to set up the Dexcom G5 Mobile App and for reordering.

If you haven't already done so, go to dexcom.com and set up your own account.

Or, if you prefer, the Dexcom G5 Mobile App walks you through creating your log in credentials as part of your initial app set up.

Summary

Now You Can:

- Describe different training resources
- Locate tutorials about using a real-time CGM in your diabetes management
- Find Dexcom G5 Mobile System's step-by-step instructions
- Recall how to use the user guide
- Explain why you need a Dexcom account

What's Next?
Now you are familiar with how to use this user guide and where to go for help.

Throughout the user guide you'll see color-coded boxes containing Safety Statements. The next chapter, Indications for Use and Safety Statement, lists all Safety Statements along with how to read and interpret them.

Next you'll learn about when and how to use the Dexcom G5 Mobile CGM System safely.

Page intentionally left blank

Chapter 2

Getting Started:
Indications for Use and Safety Statement

2.1 Introduction

We want the Dexcom G5 Mobile CGM System to be a valuable tool in your diabetes management. Like any system, there are steps to take to get the most out of it. As excited as you are about getting started, did you know if you just took Tylenol®, maybe you should wait? Did you know taking Tylenol is contraindicated?

In this chapter, you'll learn about some key areas that might prevent you from having the best CGM experience, or, if you're not careful, might even harm you or the system. You'll even learn what a contraindication is!

2.2 Important User Information

Each part of your system has instructions including indications, contraindications, warnings, precautions, and other important user information. Please review the instructions for each part of the system in this user guide before using any of the Dexcom G5 Mobile CGM System.

This chapter is important to read. It helps you use the Dexcom G5 Mobile CGM System safely and covers:

- What is a Safety Statement?
  - Telling the difference between an indication and a contraindication
  - Explaining why warnings are so important
  - Defining precautions
- How to read a chapter's Safety Statement
- Overview of Safety Statements

Let's start with definitions, look at a Safety Statement example used throughout the User Guide, and then review the Safety Statements broken down into the system's components.

Safety Statement

A Safety Statement is a brief statement of the Dexcom G5 Mobile CGM System's indications, relevant warnings, precautions, or its contraindications (when to avoid using it). The Safety

Statements are meant to keep you and the system safe while using the Dexcom G5 Mobile CGM System:

1) Indications
How, for what purposes, and under what circumstances you should use the Dexcom G5 Mobile CGM System. Indications let you know who should use the Dexcom G5 Mobile CGM System and when. Indications are the who, what, and why of the Dexcom G5 Mobile CGM System.

2) Contraindications
Contraindications let you know when ***not*** to use the Dexcom G5 Mobile CGM System. If used during these situations, you may hurt yourself or the system, the risk of use clearly outweighs the benefit.

3) Warning
Important hazard information: Describes serious or life threatening circumstances to stay away from while using the Dexcom G5 Mobile CGM System, their consequences, and how to avoid danger.

4) Precaution
Special steps you need to take while using the Dexcom G5 Mobile CGM System, preventing minor or moderate injury to either you or the system.

2.3 Safety Statements

This user guide presents Safety Statement two ways:

1. In this chapter's Overview of Safety Statements
    - Lists all Safety Statements
    - Includes a section reviewing how the statements are formatted
2. Within a chapter
    - Lists only those statements applicable to the chapter

Chapter's Safety Statements

Each chapter will list all applicable indications, contraindications, warnings, and precautions.

Some chapters will have multiple Safety Statements; others have none. Safety Statements are located towards the front so you can keep them in mind as you learn about that chapter's topic. The same statement may be repeated throughout the user guide. It's important to recognize which factors could prevent the system from working correctly, or even harming you.

Within chapters, each color coded Safety Statement is in a box, broken down into four sections:

1. Type of statement
    a. **Bold** and color-coded
        - **WARNING-Red**
        - **PRECAUTION-Blue**
        - **INDICATION-Green**
        - **CONTRAINDICATION-Purple**
2. Do's/Don'ts
    a. An action you should or should not take
    b. *Italicized*
3. Why
    a. A statement of the potential harm
4. Consequences
    a. What could happen if you don't follow the instructions

The following is an example of a chapter's Safety Statement and how to read it.

WARNING

Do: *Calibrate at least once every 12 hours.*

Why: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings.

Consequences: Missing severe low (hypoglycemia) or high (hyperglycemia) Alarm or Alerts.

Since this is a **WARNING**, you know it covers important safety information. Italics are the **Do/Don't** steps to follow: *Calibrate at least once every 12 hours.* Below the italics is a statement explaining **Why** you need to follow the steps: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings. And finally what happens, or the **Consequences**, if you don't: missing a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

2.4 Overview of Safety Statements

This section provides a review of Safety Statements containing the same elements described above (type of Safety Statement, an action, a statement of potential harm, and consequences) listed in a narrative, not boxed, format. Here you'll learn what indications

and contraindications are and what to do to keep you safe and the system in proper working order.

Safety Statements are broken down into two major categories. First, general CGM system Warnings—reviews warnings and precautions you take with most CGM systems—and second, Hardware/Software Warnings and Precautions list warnings and precautions specific to the Dexcom G5 Mobile CGM System components.

Indications and Contraindications

Indications

What are the Dexcom G5 Mobile CGM System indications? Well, in technical terms, the indications are:

The Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System is a glucose monitoring system indicated for detecting trends and tracking patterns in persons (**age 2 years and older**) with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G5 Mobile CGM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G5 Mobile CGM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G5 Mobile CGM System results should be based on the trends and patterns seen with several sequential readings over time.

In Layman's Terms
But what does that mean? Indications are the who, what, and why of the Dexcom G5 Mobile CGM System.

Who
The Dexcom G5 Mobile CGM System is a single patient use device (meaning you can't share the components with others) for people 2 years or older with diabetes.

What
The Dexcom G5 Mobile CGM System is a prescription-only glucose monitoring device. Dexcom G5 Mobile CGM System tracks your glucose patterns and detects trends. Working with your home blood glucose (BG) meter, the system is meant to complement, not replace, your BG meter.

Why

The CGM system's trend and pattern information, its glucose Alarm/Alerts, combined with your meter's actual BG value, can help you manage your diabetes.

By identifying low and high glucose level periods, the Dexcom G5 Mobile CGM System allows you to take action when needed and create long-term management strategies with your healthcare professional. Using trend information to see your highs and lows helps you stay inside your target range.

The Dexcom G5 Mobile CGM System's trend and pattern information is based on a series of sensor glucose readings taken over a period of time.

Work with your healthcare professional and create a game plan on how to best use your trend and pattern information in managing your diabetes.

Contraindications

Contraindications let you know when not to use the Dexcom G5 Mobile CGM System; you may hurt yourself or damage the system. Remember, if used during certain situations, the risk of use may clearly outweigh any potential benefit. Within the chapters, contraindications are in purple boxes.

MRI/CT/ Diathermy

Remove the Dexcom G5 Mobile CGM System (sensor, transmitter, and receiver) before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

The system hasn't been tested during MRI, CT scans, or with diathermy treatment. Magnetic fields and heat could damage the components, stopping sensor glucose readings or Alarm/Alert notifications. Without sensor glucose readings or Alarm/Alert notifications, you might miss a severe low or high glucose event.

Medications

Taking medications with acetaminophen (such as Tylenol or Excedrin® Extra Strength) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and is different for each person.

2.5 General CGM System Warnings

Warnings

Warnings outline important hazard information, describing any serious and/or life threatening situations, their consequences, how to avoid danger while using the system and how to protect the Dexcom G5 Mobile CGM System from harm.

Review Training Materials
Thoroughly review the training materials included with your Dexcom G5 Mobile CGM System before using.

Incorrect use could lead you to misunderstand system information or might affect its performance and you might miss a severe low or high glucose event.

Treatment Decisions
The Dexcom G5 Mobile CGM System does not replace your BG meter.

When making treatment decisions, such as the amount of insulin you need, only use your BG value. Don't use the Dexcom G5 Mobile CGM System sensor glucose readings because readings can be different from your BG value. If sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

Don't Ignore Low/High Symptoms
If your sensor glucose readings don't match your symptoms, measure your BG with a fingerstick. You may miss a severe low or high glucose event.

Who Shouldn't Use
The Dexcom G5 Mobile CGM System was **not evaluated** for the following persons:

- Pregnant women
- Persons on dialysis

Do not use the Dexcom G5 Mobile System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients.

The system's accuracy hasn't been tested in people falling into these groups and sensor glucose readings may be inaccurate, resulting in missing a severe low or high event.

2.6 Calibration Warning and Precautions

Calibration is the process of making sure your sensor continues to be accurate. Your sensor doesn't automatically know what your glucose levels are—you have to teach your system what a given BG value is by entering in a KNOWN glucose value from your BG meter.

Warning

Calibrate on Schedule
Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, resulting in you missing a severe low or high glucose event.

Precautions

Be Accurate, Be Quick
Enter the exact BG value displayed on your BG meter within five minutes of a fingerstick.

Entering the wrong BG values, or waiting more than five minutes before entry, might affect sensor performance, resulting in you missing a severe low or high event.

Significant Glucose Rate Changes
Don't calibrate when your BG is changing at a significant rate: more than 2 mg/dL per minute.

Look for rate of change arrows on your display device screen and don't calibrate when you see:

- A single arrow, pointing up
  - Rising 2-3 mg/dL each minute
- Two arrows pointing up
  - Rising more than 3 mg/dL each minute
- Single arrow pointing down
  - Falling 2-3 mg/dL each minute
- Two arrows pointing down
  - Falling more than 3 mg/dL each minute

Calibrating during a significant rise/fall of your BG may affect accuracy of sensor glucose readings, resulting in you missing a severe low or high glucose event.

Fingerstick Only
Only use fingerstick measurements from your BG meter for calibration.

Alternative site BG values from your arms, palm of your hand, etc., may be different and less accurate than your fingerstick BG values. Using alternative for calibration might affect sensor performance, resulting in you missing a severe low or high glucose event.

Prior to Initial Calibration: Data/Alarm/Alert
After starting a new sensor session, until completing your initial calibrations you won't receive any sensor information such as readings, Alarm or Alerts. Without these, you may miss a severe low or high glucose event.

Continue to take fingerstick measurements during a new sensor warmup period.

Now that we have reviewed common CGM Safety Statements, let's focus the Dexcom G5 Mobile CGM System components.

2.7 System/Hardware/Software Warnings and Precautions

In this section, you will learn how to safely use the Dexcom G5 Mobile CGM System's hardware and software. Some sections have either Precautions or Warnings, others will have both.

Sensor/Sensor Pod Warnings and Precautions

Warnings

Sensor Breaking Off
On rare occasions, the sensor wire may break or detach from the sensor pod.

Within 24 hours of experiencing a broken sensor wire, please call our 24/7 Technical Support department, toll free at **1.877.339.2664** or toll at **1.858.200.0200**.

If a sensor wire breaks under the skin with no portion of it visible, don't remove it. Contact your healthcare professional if you have redness, swelling, or pain at the insertion site.

Placement
Do not insert the sensor component of the Dexcom G5 Mobile System in a site other than the belly/abdomen (ages 2 years and older) or the upper buttocks (ages 2 to 17 years). The placement and insertion of the sensor component of the Dexcom G5 Mobile System is not approved for other sites.

If placed in other areas, the Dexcom G5 Mobile System may not function properly.

Storage
During a sensor's shelf life, store it between 36° F-77° F. While you don't need to keep your sensor in a refrigerator, you can as long as the refrigerator is between 36° F-77° F.

Never store sensors and/or sensor packages in a freezer.

Storing the sensor incorrectly might cause the sensor glucose readings to be incorrect, resulting in you missing a severe low or high glucose event.

Precautions

Expiration Date
Don't use expired sensors. Before inserting, always check the package label for the expiration date using the YYYY-MM-DD format.

If past the expiration date, don't use because the sensor glucose readings might not be accurate, resulting in you missing a severe low or high glucose event.

Sensor Package
Don't use sensor if its sterile package has been damaged or opened. Using a non-sterile sensor might cause infection.

Clean and Dry Before Using
Before opening the sensor package, wash your hands with soap and water, then dry. If your hands are dirty while inserting the sensor, you may contaminate the insertion site and get an infection.

Before sensor insertion, clean the skin with alcohol wipes to prevent infections. Don't insert the sensor until the cleaned insertion site is dry, and free from any lotions or perfumes.

If your insertion site is not clean and completely dry, you run the risk of infection or the sensor pod not sticking and falling off.

Sensor Placement
Change the site where you place the sensor with each new insertion. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.

Sensor placement is important. Make sure the area you place your sensor won't:

- Be bumped, pushed, or squeezed
- Have scars, tattoos, or irritation

Insertion in these areas might affect sensor performance, resulting in you missing a severe low or high glucose event.

Avoid injecting insulin or placing an insulin pump infusion set within three inches of the sensor. The insulin might affect sensor performance, resulting in you missing a severe low or high glucose event.

Transmitter Warnings and Precautions

Warnings

Inspect Transmitter
If your transmitter is damaged or cracked in any way, don't use it. Damaged components could create an electrical safety hazard or malfunction, which might cause electrical shocks.

Choking
The transmitter is small and may pose a choking hazard. Don't put it in your mouth or allow children to play with it.

Precautions

Reusable: Don't Throw Away
When ending a session, *don't throw away the transmitter.*

The transmitter is reusable and can be used in multiple sensor sessions. Keep using it until the system notifies you the transmitter battery is about to expire.

Don't Share Your Transmitter
Never share your transmitter with another person. The Dexcom G5 Mobile CGM System is a prescription-only medical device and is meant, or indicated, for your use only.

Your transmitter is tied to *your* readings. If used by someone else, your reports, Alarm and Alerts, etc., would be wrong, resulting in you missing a severe low or high glucose event.

System Precautions

Next are precautions for the receiver, transmitter, sensor and the system.

Precautions

Use Correct Transmitter, Receiver, and Sensor
Different generations' transmitters and receivers aren't interchangeable with each other.

The Dexcom G5 Mobile CGM System's transmitter and receiver are not compatible with the Dexcom G4® PLATINUM CGM System's transmitter and receiver. The Dexcom G5 Mobile CGM System won't work if you mix receiver and transmitter components from different generations, resulting in you missing a severe low or high glucose event.

You can use a Dexcom G4® PLATINUM Sensor with the Dexcom G5 Mobile CGM System. Before using the sensor, make sure the sensor label says “Dexcom G5 Mobile/G4 PLATINUM Sensor,” or “Dexcom G4 PLATINUM Sensor.”

System Accuracy
System accuracy may be affected when your glucose is changing at a significant rate such as during exercise or after a meal.

Significant glucose rise/fall rates:

- Rising 2-3 mg/dL each minute
- Rising more than 3 mg/dL each minute
- Falling 2-3 mg/dL each minute
- Falling more than 3 mg/dL each minute

Receiver and Smart Device Precautions

The Dexcom G5 Mobile Receiver and your smart device share some warnings and precautions.

Precautions

Communication Range
Do not separate the transmitter from the receiver or smart device by more than 20 feet. The transmission range from the transmitter to receiver or smart device is up to 20 feet without obstruction.

Types of obstruction differ and not all have been tested. Obstructions can include water, walls, metal, etc. If your transmitter and display device(s) are more than 20 feet from each other or are separated by an obstruction, they might not communicate, resulting in you missing a severe low or high glucose event.

Water is often the biggest culprit in reducing the communication distance between the transmitter and display devices. Take special care when swimming, getting into a pool, bathtub, shower, etc.

Setting Alarm/Alert Notifications
When using both a receiver and a smart device, you must set your settings separately in each. If you set up one device and then use another, you might not get an Alarm or Alerts, causing you to miss a severe low or high glucose event.

Using an accessory device (like a smart watch) might override your smart device sounds. Alarms or Alerts might vibrate or be heard on the accessory instead of your smart device.

After connecting any accessories, make sure that the smart device settings allow you to continue receiving Alarms or Alerts on the smart device.

Is It On?
If the receiver or smart device is turned off (Shut Down), it will not display sensor data, information, Alarm or Alerts. Make sure they are turned on; otherwise you won't get sensor glucose readings or Alarm or Alerts, causing you to miss a severe low or high glucose event.

Smart Device Warnings

Next are warnings for just your smart device.

Warnings

Smart Device Settings
The Dexcom G5 Mobile App can't override your smart device's internal settings. Also, accessory devices (like a smart watch or other wearable smart devices) might override your smart device's Alerts and Alarm.

To receive Alarm or Alerts you must:

1. **Make sure** Dexcom G5 Mobile App Notifications are **turned on** in the *Setting's* menu.
2. **Verify** app hasn't been shut down.
3. **Turn** *Bluetooth* on.
4. **Turn off** *Do Not Disturb* (if available on your smart device).
5. **Restart** app after device is restarted.
6. **Set** *Volume* at a level you can hear.
7. **Do not close app**, always run app in the background.
8. **Make sure** accessory devices do not override your smart device settings.

If your settings are incorrect, you might miss a severe low or high glucose event.

Dexcom G5 Mobile CGM System Alarm/Alert vibrations aren't any different from other vibrating apps on your smart device. Medical device apps, like the Dexcom G5 Mobile App, don't have any special priorities over your smart device's features. Dexcom G5 Mobile App notifications or alerts may sound or feel the same as notifications from another app. The only way to know is look at the screen.

Can't Hear Your Alarm or Alert?
An Alarm or Alert can't be heard through your smart device's speakers if headphones are plugged in.

Make sure you unplug your headphones when you are done using them, otherwise you might not hear an Alarm or Alert, causing you to miss a severe low or high glucose event.

Receiver Warning and Precaution

Warning

Don't Use Damaged Goods
If your receiver is damaged or cracked, don't use it. This could create an electrical safety hazard or malfunction, causing possible electrical shocks.

Precaution

Keep Receiver Dry
Keep the USB port cover on the receiver closed whenever the USB cable is not attached and do not submerge in water.

If water gets into the USB port, the receiver could become damaged and stop displaying readings or providing alerts; you might miss a severe low or high glucose event.

Caution

U.S. law restricts the sale of the Dexcom G5 Mobile CGM System to sale by or on order of a physician.

Summary

Now You Can:

- Define a Safety Statement
  - Explain the difference between an indication and a contraindication
  - Describe the importance of warnings
  - Describe what a precaution is
- Correctly read a chapter's Safety Statement
- Provide an overview of Safety Statements by category

What's Next?
In our next chapter, you will learn about the risks and benefits of using Dexcom's G5 Mobile CGM System.

Page intentionally left blank

Chapter 3

Getting Started:
Risks and Benefits

When using any medical device, there are risks and benefits. In this chapter, you'll learn what they are, helping you decide if Dexcom's G5 Mobile CGM System is right for you.

First, let's review some possible risks.

3.1 Risks

There are some risks with using real-time CGM.

Not Receiving Alarm/Alerts

If you aren't getting your CGM Alarm/Alerts, you run the risk of not knowing you are having a severe glucose low or high.

Some hardware issues preventing Alarm/Alerts:

- Alert function is turned off
- Transmitter and display device is out of range
- Receiver or smart device isn't showing sensor glucose readings
- Receiver or smart device battery is dead
- Unable to hear Alarm/Alerts or feel vibration
- App not running in the background
- Smart device is in Do Not Disturb

See Troubleshooting or recommended settings in Chapter 11 for more information.

Sensor Glucose Reading Different From Meter's

The sensor glucose reading can be different than your meter's BG value.

If the sensor's glucose reading is higher than your meter's BG value, you may miss a Low Alert. As an example, your last sensor's glucose reading was 82 mg/dL, whereas your BG value shows 78 mg/dL. If your Low Alert is set at 80 mg/dL, you won't receive an Alert because the sensor glucose reading is 82 mg/dL.

If you're not receiving an Alarm/Alert, and not taking fingerstick measurements, you may be unaware of low or high glucose levels.

Sensor Insertion Risks

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain or skin irritations (e.g., redness, swelling, bruising, itching, scarring or skin discoloration). The chance of this happening is low. The Dexcom G5 Mobile CGM System uses the same sensor as the previous CGM system—the Dexcom G4 PLATINUM. The Dexcom G4 PLATINUM System clinical studies and compliant data showed slight redness and swelling occurring only in a few patients.

During Dexcom's G4 PLATINUM System's clinical study, no sensor wires broke however there is a remote chance sensor fragments could remain under your skin if the sensor breaks during normal wear. Sterile broken sensor wires don't pose a significant medical risk.

If a sensor wire breaks off or detaches and remains under your skin, contact your healthcare professional and call Dexcom's Technical Support toll free, 24/7, at **1.877.339.2664** or toll at **1.858.200.0200** within 24 hours.

Those are the risks, let's now review the benefits!

3.2 Benefits

Daily habits impact your BG levels. With the Dexcom G5 Mobile CGM System, you can track how your exercise, carbs, stress levels, medication, or illness, influences your glucose levels.

Knowing Your Trends

Wearing the Dexcom G5 Mobile CGM System on a consistent and ongoing basis helps you manage your diabetes. Providing sensor glucose readings every five minutes, for up to seven days, the Dexcom G5 Mobile CGM System helps you detect trends and patterns. Trend information reveals where your glucose is now, where your glucose is heading, and how fast it's changing.

Understanding your trends allows you to take proactive action, helping you avoid dangerously low or high glucose values.

Using Dexcom Share (see Part 5) allows friends and family, your Followers, to monitor your glucose activity, adding another layer of support and peace of mind.

Helps in Your Diabetes Management

The Alarm/Alerts features (see Chapter 11) keep you aware of your glucose levels. Alerts notify you when your glucose goes outside your target range or is rapidly falling or rising, letting you to take action before you get too low or too high. The Urgent Low Alarm lets you know when you are dangerously or urgently low, going below 55 mg/dL. By taking corrective measures, you lessen the time spent in your low/high range, while increasing time in your targeted range (Garg S. Z., 2006) (Battelino T, 2011).

Real-time CGM can help improve your A1C as well as improve the quality of your glucose control. If you are at or below 7%, using a CGM such as Dexcom's G5 Mobile CGM System, helps reduce hypoglycemia (Tamborlane, W. V.,2008).

Lowering your A1C, increasing your time in your target range while decreasing time in low/high BG range is believed to reduce your risk of diabetes related complications (Ohkubo, Y. 1995).

In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM. (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. 2010)

What's Next?
You've read the Safety Statements, reviewed the risks and benefits; now let's take a look at Dexcom's G5 Mobile CGM System!

References:
Battelino, T., Phillip, M., Bratina, N., Nimri, R., Oskarsson, P., & Bolinder, J. (2011). Effect of Continuous Glucose Monitoring on Hypoglycemia in Type 1 Diabetes. *Diabetes Care,* 34(4), 795-800.

The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. *The New England Journal of Medicine, Vol. 329, No. 14.* (September 1993), pp. 977-986.

Garg, S., Zisser, H., Schwartz, S., Bailey, T., Kaplan, R., Ellis, S., & Jovanovic, L. (2005). Improvement in Glycemic Excursions With a Transcutaneous, Real-Time Continuous Glucose Sensor: A randomized controlled trial. *Diabetes Care, 29(1)*, 44-50.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. (2009). The Effect of Continuous Glucose Monitoring in Well-Controlled Type 1 Diabetes, *Diabetes Care, 32*(8), 1378-1383.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. (2009). Sustained Benefit of Continuous Glucose Monitoring on A1C, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes. *Diabetes Care, 32*(11), 2047-2049.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group (2010). Quality-of-Life Measures in Children and Adults with Type 1 Diabetes. *Diabetes Care, 33*(10), 2175-2177.

Ohkubo, Y., Kishikawa, H., Araki, E., Miyata, T., Isami, S., Motoyoshi, S., & Shichiri, M. (1995). Intensive Insulin Therapy Prevents the Progression of Diabetic Microvascular Complications in Japanese Patients with Non-insulin-dependent Diabetes Mellitus: A Randomized Prospective 6-year Study. *Diabetes Research and Clinical Practice, 28*(2), 103-117.

Tamborlane, W. V., Beck, R. W., Bode, B. W., Buckingham, B., Chase, H. P., Clemons, R., ... & Xing, D. (2008). Continuous Glucose Monitoring and Intensive Treatment Of Type 1 Diabetes. *The New England Journal of Medicine, 359*(14), 1464-1476.

2

LET'S G5! THE BASICS

- Introduction to the Dexcom G5 Mobile CGM System
- Initial Set-Up
- Starting a Sensor Session: Inserting the Sensor & Transmitter
- Calibration
- Ending a Sensor Session

Page intentionally left blank

Chapter 4

Let's G5! The Basics:
What Is the Dexcom G5 Mobile CGM System?

4.1 System Description

Now it's time to get an overview of the Dexcom's G5 Mobile CGM System.

After this chapter, you'll be able to:

- Explain the Dexcom G5 Mobile CGM System
- Describe options to view trends
- Locate your historical readings
- Recognize system components
- Explain each part's function

4.2 Safety Statement

If you've used the Dexcom G4 PLATINUM CGM System, you might still have its transmitter or receiver. While you can use the sensors across the different generations (look for "G5 Mobile" or "G4 PLATINUM" on the sensor's package), you can't mix the transmitter or receiver between the two systems.

WARNING

Don't: *The Dexcom G5 Mobile CGM System was not evaluated for the following persons:*

- *Pregnant women*
- *Persons on dialysis*

Do not use the Dexcom G5 Mobile System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients.

Consequences: The system's accuracy hasn't been tested in people falling into these groups and sensor glucose readings may be inaccurate, resulting in missing a severe low or high event.

PRECAUTION

Don't: *Never mix Dexcom G5 Mobile's Transmitter or Receiver with Dexcom G4 PLATINUM's Transmitter or Receiver.*

Why: The Dexcom G5 Mobile CGM System's Transmitter and Receiver are not compatible with the Dexcom G4 PLATINUM CGM System's Transmitter and Receiver. The Dexcom G5 Mobile CGM System won't work if you mix Receiver and Transmitter components from different generations.

Consequences: Missing a severe low (hypoglycemia) or high (hyperglycemia) event.

4.3 The Dexcom G5 Mobile CGM System

CGM

The Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System is a medical device you use on yourself. It allows you to continually see your sensor glucose readings, updated every five minutes for up to 7 days, without the bother of taking constant fingerstick measurement. Your sensor glucose readings are measured by a single use sensor inserted under your skin. A reusable transmitter sends your data to your display device.

The Dexcom G5 Mobile CGM System provides personalized trend alerts, prompting you to proactively react when your glucose levels are getting too low, or too high. Dexcom provides web-based reports reflecting your glucose trends and patterns. Share the reports with your healthcare professional when developing your diabetes management treatment plans.

Options to View Your Trends

The Dexcom G5 Mobile CGM System transmitter works with a number of display devices giving you flexibility to use what's best for you, your situation, or your lifestyle.

1. Dexcom G5 Mobile Receiver
2. Dexcom G5 Mobile App on your smart device

While the system works with different smart devices, they're not interchangeable during a sensor session. Before starting one, select which smart device you want to use and stick with it throughout your session. You can't use multiple smart devices at the same time, but you can combine the receiver with a smart device during a session.

The Dexcom G5 Mobile CGM System is the first CGM system where a smart device acts as a receiver. For a list of current devices and operating systems go to: **dexcom.com/compatibility**

Chapter 5 covers how to set up your smart device with the Dexcom G5 Mobile App.

The primary difference between the receiver and app is not the information they give you, but how that information is presented. The following are some of the shared CGM data and system information features.

Tracking Real Time CGM Data

The receiver and app give you the ability to track your glucose trends in a number of different ways. Each device's home screen opens to your glucose trend screen.

View Glucose Levels

The receiver and app share many of the same glucose monitoring features. Your glucose values are color coded to highlight what zone you are in, allowing you, at a glance, to see what your levels are.

Color coded glucose levels:

- Red - Low
- Grey - Within your normal range
- Yellow - High

Trend Arrows

Glucose levels are not just about the numbers. The Dexcom G5 Mobile CGM System includes trend arrows so you know the speed and direction of your glucose, allowing you to proactively react before your glucose gets too high or too low.

Alarm/Alerts

Being warned when your glucose value is too high or too low, falling or rising too quickly, or if it's trending towards a severe low or high is very important. Warnings in the form of Alerts or an Alarm help you avoid getting too low or high. Alarm and Alert notifications help keep you aware of your glucose trends and are made up of a combination of sounds, vibrations, and screens.

There are a number of Alerts, but only one Alarm: when your glucose level dips below 55 mg/dL. Some customization options are available and are part of the set up process for the receiver and smart device.

In Chapter 11, you can learn more about the Alarm and Alerts feature.

Viewing Your Glucose Values

The Dexcom G5 Mobile CGM System allows you to see your last 1-3-6-12-24 hours of your sensor glucose readings. On the receiver, from the home screen, **press** *Up/Down Arrows* to view. On a smart device, **hold upright** in *portrait* mode, and see the most recent three hours, **turn sideways** to *landscape* to view your glucose levels over the last 1-3-6-12-24 hours.

Go to Chapter 9 to learn more about viewing your glucose trends.

4.4 What's New to the Dexcom G5 Mobile CGM System?

Dexcom's G5 Mobile CGM System has features not found in our previous generations. They include:

- Dexcom G5 Mobile App for your smart device
- Updates to the Dexcom G5 Mobile Receiver screens
- Software updates
    - Dexcom Share in the Dexcom G5 Mobile App

Share Your Data

Through secure wireless connections, Dexcom Share allows remote viewing of your sensor glucose readings, trends, and data by your loved ones from a smart device. Activate Dexcom Share by tapping on the app's Share icon, follow a few simple steps, then invite up to five people to connect with you.

After downloading the Dexcom Follow™ App, they become your Follower. As a Follower, they can watch your sensor glucose readings, trends, and receive Alarm/Alerts when your glucose is low or high.

You determine what your Follower can see. Based on what you allow, your Followers can receive your Alarm or Alerts, and view your trends. Followers can pick and choose, or turn off, the data they receive, including the Alarm/Alerts, trends, and messages. The Share feature in the Dexcom G5 Mobile App is different than the Dexcom Share App used with other systems.

More information about Dexcom Share and instructions for use, go to Part 5.

> **NOTE:** Review all Dexcom Share System indications, contraindications, warnings, precautions and detailed procedures in Part 5.

4.5 System Information

The receiver and app also keep you informed on the system's status. Technical notifications provide information about your sensor session and about the system's hardware. Each chapter provides a table of the prompts, system, and error messages applicable to its subject. As an example, the calibration chapter will review all calibration messages you may see.

Now you know what the Dexcom G5 Mobile CGM System does and what's new, let's open your Dexcom G5 Mobile packages, see what's inside, and review each item.

4.6 System Components

Package

The Dexcom G5 Mobile CGM System comes to you in a number of boxes; after opening keep the packaging until you are no longer using its contents.

Sensor	
	Sensor package
	Single use sensor(s)
	Insert

(Continued on next page)

(Continued from previous page)

Transmitter	
	Transmitter package
	Reusable transmitter
Receiver	
	Receiver package
	Receiver
	Receiver's USB charging and download cable
	AC power adapter

(Continued on next page)

(Continued from previous page)

Receiver	
	Welcome Card
	Quick Start Guide
	Training Checklist attached to Quick Start Guide
	Training Tutorial USB Card

Overview of System Components

This section is meant as a quick overview of each part, specifics for each are found in following chapters. For detailed product specifications and technical information, please go to Chapter 17.

The Dexcom G5 Mobile CGM System is comprised of four key parts:

1. Single use sensor
2. Reusable transmitter
3. Rechargeable receiver
4. Dexcom G5 Mobile App
    a. Downloaded to your smart device

Dexcom G5 Mobile CGM System optional:
Dexcom Share

Sensor Overview

For your safety, the sensor is packaged in a sterile sealed pouch, containing an applicator, sensor pod, and sensor wire. When you first open the package, your sensor looks like one item, however it's actually three: sensor applicator barrel, sensor pod, and sensor wire.

The applicator barrel helps you insert the sensor wire inside the sensor pod under your skin. After inserting the sensor wire, remove the applicator barrel. The sensor wire stays in the sensor pod with the pod attached to your skin by adhesive.

The sensor wire is made of silver and platinum with polymer membranes. Once inserted, the thin and flexible wire measures your glucose levels in the fluid between your cells (interstitial fluid) for up to seven days.

This section is meant as a quick overview. More information on using and inserting the applicator, sensor, and sensor wire can be found in Chapter 6.

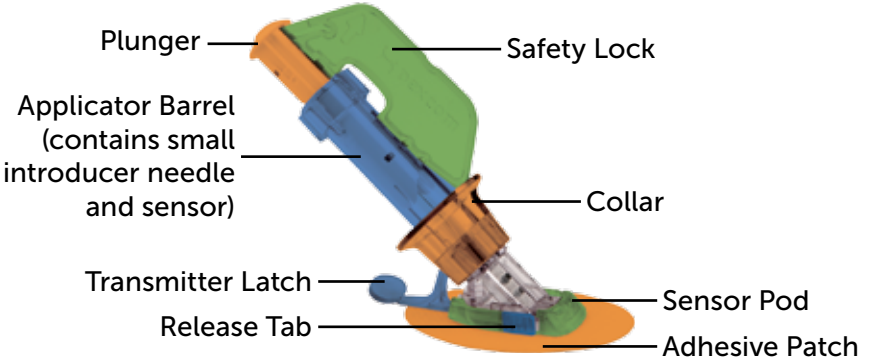


Figure 1. Dexcom G5 Mobile Sensor Applicator and Pod

Applicator and Sensor Pod

What it's called	What it does
Applicator	
Applicator Barrel	Contains small insertion needle and sensor wire. Inserts sensor wire under the skin. Disposable, for single use only. Removed after insertion.
Safety Lock	Keeps all moving parts in place before insertion. Prevents accidental sensor insertion. Tool to remove transmitter after sensor session. Put in transmitter box after removal to use later.
Collar	Collar removes insertion needle.
Plunger	Inserts sensor wire into your body.
Transmitter Latch	Securely snaps transmitter into sensor pod.
Sensor Pod	
Sensor Pod	Holds transmitter and sensor wire. Water resistant when transmitter is properly installed. Discarded after sensor session.
Adhesive Patch	Keeps sensor pod attached to your skin.
Transmitter Cradle	Holds transmitter in place during sensor session.
Sensor Wire	Wire measures glucose levels in fluid in between your cells. Attached to sensor pod. Discarded with pod after session.

Transmitter Overview

Figure 2. Dexcom G5 Mobile Transmitter Front and Back

Snapping into the sensor pod, the gray plastic transmitter wirelessly sends your glucose information to your display devices—receiver and/or smart device. If you have a new transmitter, open the package when you are ready to use it.

The transmitter is:

1. Reusable
    a. Do not discard after sensor session.
    b. Only for you, don't share transmitter.
2. Water resistant
3. Can transmit data to your display devices for up to 20 feet
    a. Range is less if you are in or under water.
4. Battery lasts approximately three months
    a. Receiver or smart devices prompts you when battery is running low.
5. Transmitter's serial number is on the back

More transmitter features and insertion information is in Chapter 6.

Now you are familiar with sensor and transmitter, let's review the Dexcom G5 Mobile Receiver.

Dexcom G5 Mobile Receiver

The receiver is a small hand-held device. Your receiver, along with your smart device, shows your sensor glucose readings, trend graphs, trend arrows and alerts you when your glucose is too high or too low or if there is something you should be aware of or need to do.

The receiver is neither water resistant nor waterproof and can get damaged if moisture gets inside, so keep it away from any liquids and very high humidity. Keeping the micro USB port closed helps prevent damaging fluids and dust from getting inside the receiver. If your receiver does get wet, test it to make sure the speaker and vibrations still work (see Chapter 12).

If your receiver isn't charged, see Chapter 14 for charging your receiver's battery.

If you want to use the receiver along with a smart device, you need to set them up separately.

Remember, you can't use a combination of smart devices during a sensor session; select just one.

Receiver Overview

What you see	What it's called	What it does
	Receiver	Provides data about your glucose trends via screen display, sounds and vibration.
	Micro USB Port	**Plug** *USB cable* into *port* for recharging.
	USB Port Door	**Close** *USB port door* after removing *USB cable* to keep receiver clean and dry.
	Micro USB Cable	**Plug** into *receiver* to charge battery. Don't plug into a computer port to charge. Battery can only be charged using the adapter/wall charger.

(Continued on next page)

(Continued from previous page)

What you see	What it's called	What it does
	Wall Charger	**Plug** *USB cable* into *adapter/wall charger.* Plug wall charger into an electrical outlet to charge receiver's battery. Don't block access to the charger.
	Display Screen	Shows sensor glucose readings, trend graphs and arrows, Alarm/Alerts, sensor session status. Change settings on Menu screen.
	Speaker	Allows you to hear your Alarm/Alerts sounds.
	Navigation Wheel	Arrows and button to help you navigate through the receiver's menu options and choose features.
	Select Button	**Press** to select menu option.
	Left Arrow	**Press** to go back to last item/screen or home screen.
	Right Arrow	**Press** to highlight next item.

(Continued on next page)

(Continued from previous page)

What you see	What it's called	What it does
	Up/Down Arrows	**Press** to scroll up or down to select menu items or set values. **Press** to scroll back and forth beyond from the 3 hour trend graph to the 1-6-12-24 views.

4.7 Smart Device Overview

The Dexcom G5 Mobile App was created to work with your smart device, giving you even more options in monitoring your glucose trends and patterns. The app is similar to all other apps.

This User Guide is not meant to show you how to use your smart device. Please contact your smart device support or read your smart device's user guide for assistance.

Summary

Now You Can:

- Explain the Dexcom G5 Mobile CGM System
- Describe options to view trends
- Locate your historical readings
- Recognize system components
- Explain each part's function

Next Steps

Your next step in getting started with the Dexcom G5 Mobile CGM System is selecting how to continuously receive your sensor glucose readings: Dexcom G5 Mobile App, the Dexcom G5 Mobile Receiver or a combination.

Our next chapter helps you set up both!

Page intentionally left blank

Chapter 5

Let's G5! The Basics:
Set up Your Display Devices

5.1 Introduction

In the previous chapter, you received a high level overview of the Dexcom G5 Mobile CGM System and learned you can monitor your glucose levels with different display devices. Now it's time to set up your Dexcom G5 Mobile App and your receiver.

After this chapter, you will be able to:

- Create a Dexcom username and password
- Download the Dexcom G5 Mobile App
- Set up the Dexcom G5 Mobile App with the recommended settings
- Successfully set up your Dexcom G5 Mobile Receiver

5.2 Safety Statement

If you've used the Dexcom G4 PLATINUM CGM System, you might still have its transmitter or receiver. While you can use the sensors across the different generations (look for the Dexcom G5 Mobile/G4 PLATINUM Sensor package), you can't mix the transmitter or receiver between the two systems.

PRECAUTION

Don't: *Never mix Dexcom G5 Mobile's Transmitter or Receiver with Dexcom G4 PLATINUM's Transmitter or Receiver.*

Why: The Dexcom G5 Mobile CGM System's Transmitter and Receiver are not compatible with the Dexcom G4 PLATINUM CGM System's Transmitter and Receiver. The Dexcom G5 Mobile CGM System won't work if you mix Receiver and Transmitter components from different generations.

Consequences: Missing a severe low (hypoglycemia) or high (hyperglycemia) event.

5.3 Why Different Monitoring Methods?

Your convenience!

By offering two separate monitoring systems, the app or receiver, you can choose to monitor your glucose levels in the handiest method at that moment. Smart device ran out of memory. If you forgot your receiver at home, use your smart device! Battery died on your smart device? Smart device memory full? Your receiver has you covered!

With the exception of Dexcom Share, the primary difference between the two monitoring systems is not the data itself, but how it's presented.

The next section walks you through the initial set up for the app. To set up the receiver, go to Section 5.5. If you want to use both the mobile app and the receiver, you need to set each up individually.

Once you have completed the initial set up, you're one step closer to beginning your sensor session!

5.4 Dexcom G5 Mobile App

Before starting your first sensor session, pick the smart device you want to use. As mentioned in the previous chapter, you can use the receiver with one smart device during a session; however, you can't use multiple smart devices during the same session.

While your smart device can have the app installed, part of your initial set up is entering the transmitter's serial number (SN). If by accident you enter the SN into more than one smart device, the system warns you and you won't be able to complete the set up process.

Suggested Smart Device Settings

Bluetooth is designed wireless communication between devices (unlike Wi-Fi®, which wirelessly connects devices to the Internet). Your transmitter communicates to your app via *Bluetooth®* Smart! Before beginning, **make sure your smart device's *Bluetooth* is available and turned on**.

Refer to your smart device's user guide if you have questions on how to change your smart device settings.

- While checking your *Bluetooth* settings, check to see *Silent* and *Do Not Disturb* are off. Your app does not override these settings; **if you have them on, you will miss Alarm/Alerts**
- After verifying all your settings are correct, there is one more thing to check. Make sure your smart device's *Volume* is loud enough for you to hear any Alarm/Alerts

- Make sure your smart device settings allow your Dexcom Alarm/Alerts to always show on your lock screen
- For information on how to set the above settings, see your smart device's user guide. Once you have verified your smart device's settings are right, the next step is installing the Dexcom G5 Mobile App
- The app needs to be open and running in the background. This may drain your smart device's battery; make sure you check its battery is charged
- Don't change your smart device's time because it can make the time on the trend screen wrong and the app may stop displaying data

If your smart device is broken or lost, use receiver until it's fixed or replaced.

Dexcom G5 Mobile App Installation

Installing the app is easy! Simply download the Dexcom G5 Mobile App from your smart device's store. However, if your smart device has been jailbroken, do not install the app.

For information on how to install an app, see your smart device's user guide.

Initial Dexcom G5 Mobile App Setup

Setting up your app is easy! You'll need your Dexcom account *username* and *password*, along with your *transmitter box*. Once inside, simply follow the set up wizard instructions. The set up wizard walks you through safety information, recommended settings, entering transmitter SN, setting your high/low glucose levels, and receiving CGM notifications.

Your initial set up will require a Dexcom username and password. You can create them by **tapping** *Sign Up* within the app, or by going to dexcom.com.

From Your Web Browser:

1. **Go** to *dexcom.com*.
2. **Click** green *Get Started* tab or the three green bars, then "Get Started."
3. **Click** green *Get Started* button on the page.
4. **Fill out** *User account* screen.
5. **Click** the green *Create New Account* button towards the bottom of the screen.

But what if you are unclear about a step?

The Dexcom App has prompts allowing you to get more information. If you are unsure of something during your initial set up process, look at the screen for additional information prompt. Informational prompts include, but aren't limited to: *I don't understand, Learn More, or Question Mark*. **Tap** your *informational prompt* to get more information.

To close out of the information prompt, **tap** the *X* in the upper right hand corner.

Initial App Setup

Step	What you see	What you do
Introductory Screens		
1		**Tap** *Dexcom G5 Mobile App* icon to open app.
2		**Swipe** through introductory screens or **tap** *Log In*.

(Continued on next page)

(Continued from previous page)

Introductory Screens		
3		**Enter** existing username and password OR Need a Dexcom username and password? **Tap** *Sign Up*. **Complete** *Username/Password* fields. **Tap** *Login* once.
4		**Tap** *Let's Get Started*.

(Continued on next page)

(Continued from previous page)

Introductory Screens		
5		The next screens are the Terms of Use, safety warnings, contraindications, and the recommended settings. Once each screen is read, **tap** the *appropriate answer* to move forward. **Tap** *Full Safety Statement* or, when applicable, *I don't understand* to get more information.

(Continued on next page)

(Continued from previous page)

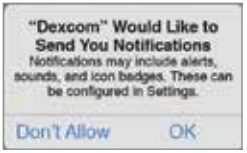
Setting up Your App Alarm/Alerts and Basic Settings

6		**Set** your *Low Glucose Alert*. Default is 80 mg/dL. *Scroll* to select another amount. **Tap** *Save* to move forward. Once set, you'll receive an Alert notification if your glucose dips below your set amount.
7		**Set** your *High Glucose Alert*. Default is 200 mg/dL. **Scroll** to select another amount. **Tap** *Save* to move forward. Once set, you'll receive an Alert notification if your glucose rises above your set amount.

(Continued on next page)

(Continued from previous page)

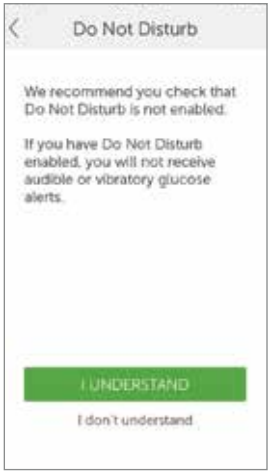
Setting up Your App Alarm/Alerts and Basic Settings

8a		Make sure you get your Alarm/Alerts notifications. **Tap** the *appropriate response* to move forward and set your notifications.
8b		**Tap** *OK* to receive Alarm/Alerts notifications.

(Continued on next page)

(Continued from previous page)

Setting up Your App Alarm/Alerts and Basic Settings

9		The next screens provide suggestions for device volume, *Do Not Disturb*, and other basic settings. **Tap** *appropriate answer* to move forward.

(Continued on next page)

(Continued from previous page)

Connecting/Pairing Transmitter With App

10		**Tap** *Next*.
11		**Verify** *Bluetooth* is on. The app will check to see if *Bluetooth* is turned "on."

(Continued on next page)

(Continued from previous page)

Connecting/Pairing Transmitter With App		
12a		**Get** your *Transmitter* box. **Tap** *Take Photo*.
12b		**Turn** *transmitter box* **upside down** on a flat surface with barcodes facing up. **Center** longest *barcode* within green brackets.

(Continued on next page)

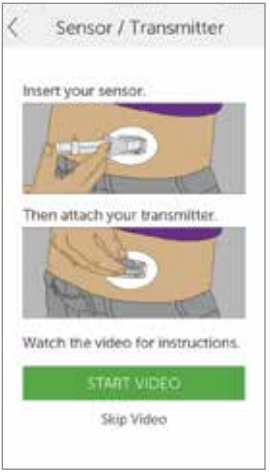
(Continued from previous page)

Connecting/Pairing Transmitter With App		
12c		Check mark confirms successful transmitter SN scan.
13a		If unable to use app's scanning device: **Tap** *Enter transmitter SN by hand.*

(Continued on next page)

(Continued from previous page)

Connecting/Pairing Transmitter With App

13b		**Use** keyboard to enter transmitter SN. **Confirm** correct SN . **Tap** *Save*.
14		Insert sensor and attach transmitter following video's instructions. See Chapter 6 for more information.

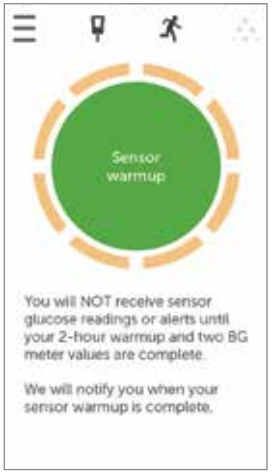
(Continued on next page)

(Continued from previous page)

Connecting/Pairing Transmitter with App		
15		**Wait** up to 30 minutes for smart device and transmitter to connect.
16		At prompt, **Tap** *Pair* to pair app with smart device.

(Continued on next page)

(Continued from previous page)

Connecting/Pairing Transmitter with App		
17		**Tap** the *Sensor warmup* circle to start your two hour sensor warmup. When you see the sensor warmup timer, your initial set up is complete. Congratulations!

If you have any issues setting up the Dexcom G5 Mobile App, call Technical Support toll free at **1.877.339.2664** or toll at **1.858.200.0200**. We are here 24/7 to assist you.

If you are having problems with your smart device, contact your smart device's support line.

After completing your initial app setup, set up the receiver or go to Chapter 6 to start your initial sensor session.

5.5 Dexcom G5 Mobile Receiver

In the previous chapter, you learned about the receiver's components. The following is a refresher to help in your initial set up.

Display Screen:

- Trend screen
- Menu selection screen

Navigation Wheel:

- Select
  - Button in the middle of the navigation wheel

        - Center button does not say “Select”
    - Press to
        - Turn on receiver
        - Select options/features
        - Accept changes
        - Move forward through menus/features
- Up/Down
    - Scroll through trend screens
    - Highlight menu items
    - Change values
- Left
    - Go back to last item or screen
- Right
    - Go to next item or screen

Initial Setup of the Dexcom G5 Mobile Receiver

Press *Select* to turn receiver on.

The first screen you see is the startup screen with ascending green bars. Once complete, a set up wizard guides you through the initial set ups steps. Don’t be alarmed if your receiver buzzes or makes other sounds during this process.

After your initial setup is complete, you won’t see the setup wizard again. Your settings can always be adjusted using menu options.

How you complete your initial set up differs between the receiver and your smart device; however, the data is the same.

Setup Wizard Prompts:

- Time/Date
- Transmitter Serial Number
    - Back of transmitter
    - Back of transmitter’s box
- Setting Low Alert
- Setting High Alert

Before starting a session, you may want to check the receiver’s battery level. If it is less than half, go to Chapter 4, for charging instructions.

Initial Receiver Set up

Step	What you see	What you do
Initial Screens		
1		**Press** *Select* to turn receiver on.
2		**Wait**.
Time/Date		
3a		**Press** *Up/Down Arrow* to change year. **Press** *Right Arrow* to move forward. **Press** *Up/Down Arrow* to change month. **Press** *Right Arrow.* **Press** *Up/Down Arrow* to change day. **Press** *Right Arrow* to move to time.

(Continued on next page)

(Continued from previous page)

Time/Date		
3b		**Press** *Up/Down Arrow* to change hour. **Press** *Right* Arrow. **Press** *Up/Down Arrow* to change minutes. **Press** *Right* Arrow. **Press** *Up/Down Arrow* to select AM/PM. **Press** *Select* to save and close. **NOTE:** After initial set up, if battery is drained, receiver will vibrate once and you will need to reset date and time.
Transmitter		
4a		**Turn** *transmitter box* **upside down** to locate SN number.
4b		If transmitter package isn't available: • SN is on transmitter's back
4c		**Press** *Up/Down Arrows* to select and enter transmitter SN. **Press** *Right Arrow* to move to next digit. **Press** *Select* to save and close.

(Continued on next page)

(Continued from previous page)

Setting Low Alert		
5a		System default is at 80 mg/dL. **Press** *Select* to save at present levels and close.
5b		To change value: **Press** *Up/Down Arrows* to change value at 5 mg/dL increments. **Press** *Select* to save and close.
Setting High Alert		
6a		System default is at 200 mg/dL. **Press** *Select* to save at present levels and close.
6b		To change value: **Press** *Up/Down Arrows* to change value at 10 mg/dL increments. **Press** *Select* to save and close.

These steps are enough to get you going; now you can start your sensor session!

Summary

Now You Can:

- Create a Dexcom username and password
- Download the Dexcom G5 Mobile App

- Set app up with the recommended settings
- Successfully set up your Dexcom G5 Mobile Receiver

What's Next?

Now you have completed setting up your app and/or the receiver, your next step is starting a sensor session.

No matter what monitoring method you choose, starting a sensor session is the same:

1. Inserting the sensor.
2. Inserting the transmitter.
3. Pairing the transmitter to your device.
4. Two hour sensor warmup.
5. Initial calibrations.

Chapter 6

Let's G5! The Basics:

Starting a Sensor Session: Inserting Sensor, Transmitter, and Starting Your Session

6.1 Overview

Now that your display devices are set up, you're ready to begin a sensor session. If this is your first time inserting a sensor, you may want to watch the Dexcom G5 Mobile sensor insertion video to get a better understanding of the process.

The Dexcom G5 Mobile sensor insertion video is available by three ways:

1. Through the App
2. USB card in your Dexcom G5 Mobile Receiver package
3. Online at dexcom.com:
    a. Top of page, **click** *Support Tab*.
    b. **Click** *Education*.

After inserting the sensor, start the sensor warmup on your smart device and receiver. The sensor warmup takes approximately two hours; during this time your body is getting used to the new sensor, allowing for more accurate sensor glucose readings. Once the two hour sensor warmup has passed, you enter two back-to-back fingerstick measurements to calibrate the sensor's glucose readings with your fingerstick measurements (Calibration is covered in the next chapter).

Make sure you give yourself enough time to finish the startup session. Remember your smart device's *Bluetooth* needs to pair with the transmitter, adding up to 30 minutes to your wait time. Good news is you don't need to sit around waiting: as long as you have your display device near, you can go about your day running errands, gardening, personalizing the Dexcom G5 Mobile settings, whatever you choose during that time frame.

Keep your display device(s) handy during the warmup period—it shows how much time has passed, notifying you with beeps and an icon when your sensor session is ready for its initial calibrations.

After this chapter you will be able to:

- Identify sensor applicator features
- Properly prepare for sensor insertion
- Choose the best location to insert your sensor
- Correctly insert your sensor
- Prepare transmitter for placement
- Correctly attach transmitter to sensor
- Outline what happens during the sensor warmup
- Identify countdown icon

6.2 Safety Statements

Following are some important Precautions and Warnings to review; we want to make sure you and the system are safe before starting a sensor session.

WARNING

Don't: *If a sensor breaks under the skin with no portion visible above the skin, don't remove it.*
Do: *Seek professional medical help if you have symptoms of infection or inflammation (e.g., redness, swelling or pain) at the insertion site.*

Always report a broken sensor to our Technical Support, 24/7, team at as soon as possible:
Toll free: **1.877.339.2664**
Toll call: **1.858.200.0200**

Why: Sensors may fracture on rare occasions.

Testing done in a controlled environment (in-vitro) didn't find any safety hazards during an MRI with a broken off sensor under the skin. The wire didn't heat up nor have any significant movement during the MRI, images were affected only in the area around the sensor's wire.

MRI with broken wire
If you have experienced a broken sensor and are planning to take an MRI, please discuss the following with your doctor or technician.

Laboratory (in vitro) MRI tests did not detect any safety hazards for a broken sensor that remains in the body.

There was no significant movement or heating of the wire. Imaging artifacts were limited to the area around the wire.

WARNING

Do: *Store sensor between 36° F-77° F during its shelf life.*

Why: Storing the sensor incorrectly might cause the sensor glucose readings to be inaccurate.

Never store sensors in the freezer.

Consequences: If stored outside of 36° F-77° F, your sensor glucose readings may not be accurate, resulting in you missing a severe low or high glucose event.

WARNING

Don't: *Never use the Dexcom G5 Mobile CGM System sensor glucose readings for treatment decisions.*
Do: *Only use BG values from your BG meter for treatment decisions (e.g., how much insulin to take).*

Why: Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's blood glucose values.

Consequences: Using sensor glucose readings for treatment decisions could result in you missing a severe low or high event.

PRECAUTION

Do: *Select sensor insertion site with care.*

Avoid:

- Areas likely to be bumped, pushed or squeezed
- Areas of skin with scarring, tattoos, or irritation
- Injecting insulin within 3 inches of sensor
- Placing an insulin pump infusion set within 3 inches of sensor

Why: Inserting sensor in these areas may affect sensor glucose readings.

Consequences: Inaccurate sensor glucose readings may result in you missing a severe low or high event.

PRECAUTION

Do: *Check sensor package before opening.*

Why: Make sure the sterilized package has not been damaged or previously opened. If opened or damaged, sensor may be unsterile.

Consequences: Using an unsterile sensor may cause an infection.

6.3 Prepping for Sensor Insertion

Before inserting a sensor, make sure you have everything you need. Some items are included in the Dexcom G5 Mobile CGM System's packages, others are not.

Items Included in Your Dexcom G5 Mobile Packages

For sensor insertion, you need the sensor and transmitter.

Sensor Applicator

Inside Sensor Box

What you see	What it is
	Sterilized sensor pouch with important label information. **Check** *expiration date.*
	Single use sensor applicator.

Knowing what each applicator piece does helps you successfully insert your sensor. Chapter 4, Section 4.6 gave you overview of the sensor applicator.

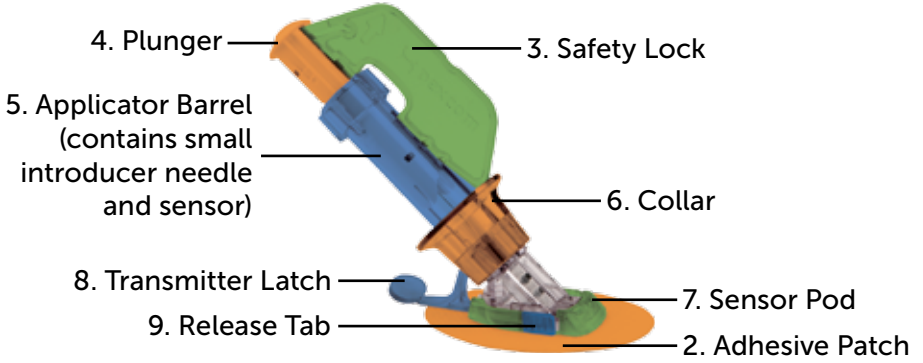


Figure 3. Dexcom G5 Mobile Sensor Applicator and Pod

The following table reviews the sensor applicator components in order of use.

Order of Use	Name	What it does
1	Sensor Pouch	Sterilized for your protection. Open to remove applicator and sensor.
2	Adhesive Patch	Holds the sensor/transmitter in place on your skin.
3	Safety Lock	Prevents plunger from inserting sensor until you are ready.
4	Plunger	Inserts sensor wire into your body.
5	Applicator Barrel	Contains small insertion needle and sensor wire. Disposable, for single use only.
6	Collar	Collar removes insertion needle. Helps remove applicator barrel once sensor wire is inserted.

(Continued on next page)

(Continued from previous page)

Order of Use	Name	What it does
7	Sensor Pod	Holds sensor wire in place under skin. Holds transmitter.
8	Transmitter Latch	Locks transmitter into sensor pod.
9	Release Tab	Allows you to remove applicator barrel from sensor pod.

Transmitter

Transmitter Box

What you see	What it is
	Bottom of box with important label information. Keep box until transmitter battery dies.
	Reusable transmitter.

In the previous chapter, you entered your transmitter SN into your display devices and made sure your smart device and/or receiver connected with the transmitter. You won't be able to start a sensor session if your transmitter isn't paired with your receiver and/or smart device.

Not included in packages:

1. Alcohol wipes
2. *Your* blood glucose meter
3. *Your* test strips

Before starting, check your blood glucose meter; make sure it's in good working order following manufacturer's directions and the meter's date and time match your display device's date and time.

Make sure test strips haven't expired and work with your meter.

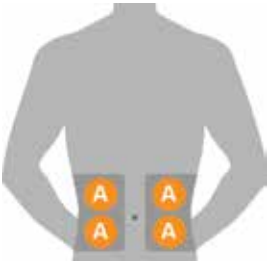
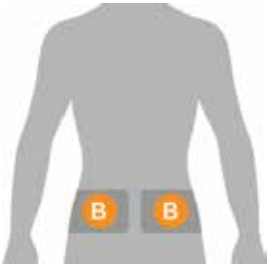
Before removing the sensor applicator out of its sterile pouch, determine the best place to insert your sensor.

6.4 Choosing Your Insertion Site

Choose a place on your belly (or if user is between the ages of 2 and 17, upper buttocks) to insert the sensor; the site should be either above or below your belt line. The best areas are usually flat, "pinchable," and free from where rubbing can occur (along the waist band, seat belt strap or where you lay when sleeping).

For more help on ideal sensor insertion sites, contact your healthcare professional.

Insertion Sites

Location	Where it is
	Front of body (belly area) for ages 2 years and above.
	If user is between the ages of 2 years and 17: Back of body (Upper buttocks)

Do:

- Remove the sensor and applicator from its sterile package only at time of use
- Place at least 3 inches from your insulin pump infusion set or injection site

- If needed, shave the area so adhesive patch sticks securely
- Make sure area is clean and free of lotions, perfumes, medications

Don't:

- Never use same site repeatedly for sensor insertion
- Never use same site for 2 sensor sessions in a row

If you have concerns about the sensor pod not sticking, before inserting your sensor, you can make the sensor site stickier to help ensure the sensor pod does not peel.

Optional Site Preparation

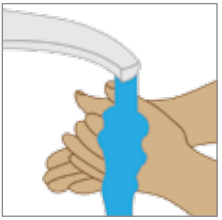
Use optional skin adhesives (Mastisol™, SkinTac™) as part of your insertion site preparation to help keep your sensor pod attached. Apply the skin adhesive after you selected and cleaned your insertion site. Use circular motions and create an "O" outline, making sure you don't get any skin adhesive inside the outline. Let the "O" dry based on skin adhesive manufacturer's instructions. Once dry, your skin may feel slightly sticky.

See Step 3 in the next table for directions.

NOTE: Contact your healthcare professional for specific questions regarding the use of medical tape, barrier wipes and/or other adhesives as it relates to your use of Dexcom CGM.

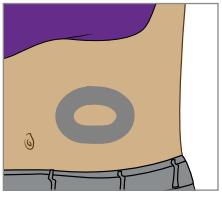
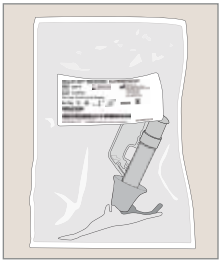
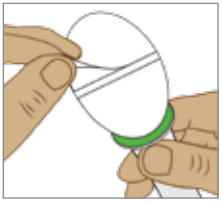
6.5 Inserting Your Sensor

You've collected all of the needed items to begin a sensor session, viewed the tutorials, reviewed the sensor applicator and prepped the sensor pod site. You're now ready to insert your sensor!

Step	Picture	What you do
Preparation		
1		**Wash** and **dry** your hands.

(Continued on next page)

(Continued from previous page)

Preparation		
2		**Clean** *insertion site* with alcohol wipe. Let dry.
3		**Optional Step: Skin Adhesive** **Create** an *oval* on the skin • Do not get any skin adhesive inside the circle • Let skin adhesive dry • Insert sensor on clean skin at the center of the circle
4		**Check** *pouch*: Is it damaged or already opened? **Remove** *sensor applicator* from sterile pouch. **Closely inspect** *sensor*, check it hasn't been damaged. **Keep** *sensor packaging* until sensor session is complete.
Attaching Sensor Pod		
5		**Pull** *adhesive backing tabs*. **Don't touch** *sticky adhesive patch*.

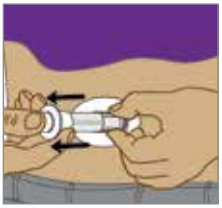
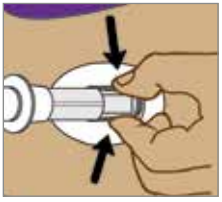
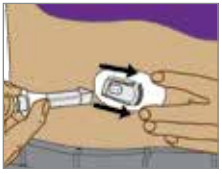
(Continued on next page)

(Continued from previous page)

Inserting Sensor Wire		
6		**Place** *sensor* horizontally, not vertically, on skin. **Move** fingers around *adhesive patch's top* several times to secure tape.
7		**Hold** *applicator barrel*. **Pull** *safety lock* out.
8		**Place** fingers of one hand on edges of *adhesive patch*. **Pinch** up your skin at the tips of the *white adhesive*.
9		**Place** two fingers directly *above* collar to steady applicator barrel. **Place** thumb on the *white plunger*. **Push** *plunger* completely down the applicator barrel. You should hear 2 clicks. **NOTE:** Finger placement is important for correct insertion.

(Continued on next page)

(Continued from previous page)

Removing Applicator Barrel and Collar		
10		**Move** two fingers from *above* collar to *below* collar. Keeping your thumb as a base on the white plunger. **Pull** *collar* all the way back towards your thumb. You should hear 2 clicks. **NOTE:** Finger placement is important for correct needle removal.
11		**Hold** *transmitter latch* down against your body. **Squeeze** *ribbed release tabs* on the sides of sensor pod.
12a		**Move** *applicator barrel* forward and out, away from your body. Follow local ordinances when disposing the applicator.
12b		**What's left?** 1. Sensor pod 2. Transmitter latch

You have successfully inserted the sensor!

At this point, you should have two items attached:

1. The sensor pod
2. The transmitter latch

Having problems?

If it's the first time inserting a sensor, you may have questions or need help. If you do, please contact your Dexcom G5 Mobile CGM System Technical Support team, 24/7, at:

- Toll free: **1.877.339.2664**
- Toll call: **1.858.200.0200**

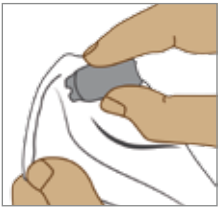
The next step is attaching your transmitter to the sensor pod.

6.6 Attaching Your Transmitter

Now that you have inserted your sensor, you need to attach your transmitter.

Since the transmitter is reusable, you don't need a new one every time you start a sensor session. Keep your current session's transmitter box. The bottom label has important information you may need after you've inserted the transmitter. Once the transmitter has been attached, you can't remove it until your session is over. Chapter 8 reviews when and how to remove your transmitter.

Before inserting your transmitter, check you entered the correct transmitter SN into your display device. Chapter 5 covers entering transmitter's SN number.

Step	Picture	What you do
1		**Remove** *transmitter* from box. **Keep** box. **Save** *safety latch* from sensor applicator (helps remove transmitter once sensor session is over). **Get** alcohol wipe.
2		**Wipe** *back of transmitter* with alcohol wipe. **Let dry** for 2-3 minutes. **Don't** let the back of transmitter touch your skin. **Don't** scratch transmitter's back, this can harm the waterproof seal.
3		Flat side down. **Slide** *transmitter's small end* under the sensor pod lip located in front of pod's ribbed tabs, away from *transmitter latch*.

(Continued on next page)

(Continued from previous page)

Step	Picture	What you do
4		**Keep** finger on *transmitter* holding it in place. **Push** *transmitter latch* up and forward over the transmitter's wide end with your other hand. You should hear 2 clicks.
5		**Is transmitter secure?** Before removing transmitter latch, verify transmitter is securely in place. Make sure none of the transmitters sides popped out of the sensor pod. If not completely snapped in, you may have a bad connection and it won't be water tight.
6		**Hold** *sensor pod sides* with one hand. **Twist** *latch* **away** from your body with other hand. **Remove** *latch*. **Don't** remove *transmitter* while sensor pod is attached to skin.

You're almost done starting your sensor session!

Inserting the sensor, attaching the transmitter, and the two hour sensor warmup are the same regardless whether you use the receiver or app.

The remaining steps vary from app to receiver:

1. Letting your device know you need to start the sensor warmup.
2. Following your warmup countdown.

6.7 Loose Sensor Pod

The sensor pod should stay on your skin using its own adhesive.

If the patch peels up, use medical tape (such as Blenderm™, Tegaderm™, Smith & Nephew IV3000®, 3M™ tape) for extra support.

- Tape over white adhesive patch on all sides for even support
- Don't tape over the transmitter or any plastic parts of the sensor pod
- Don't tape under sensor pod
- Don't leave any substance on the skin where you insert the sensor

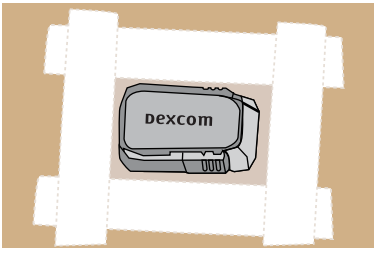


Figure 4. The Right Way to Use Tape for Extra Support

6.8 Starting Your Sensor Session

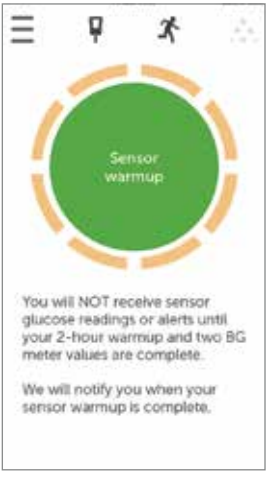
If you choose to use both the receiver and the app, each system requires individual setups (see Chapter 5).

After pairing the transmitter to your device(s), inserting your sensor, and attaching the transmitter to the sensor pod, your next step is telling your device(s) you want to start a sensor session. Transmitters are reusable; pairing is required only when using a new transmitter.

During the warmup period, neither device will provide any sensor glucose readings. Your sensor glucose readings begin after the two hour sensor warmup has passed and you entered the initial two calibration BG values into either the smart device or the receiver.

We'll first review starting the sensor session for the app.

Dexcom App: Starting a Session

Step	What you see	What you do
1		**Wait** for *Successful Pairing* notification. **Tap** *green checkmark* in black square.
2		**Tap** *Sensor Warmup* circle to start your two hour sensor warmup. **NOTE:** You will NOT get any sensor glucose readings, Alarm/Alerts during your two hour sensor warmup period.
3		**Wait**. Screen provides countdown to sensor warmup. The orange dashes darken as the countdown moves forward. **Keep** *smart device* within 20 feet of transmitter during the sensor warmup period.

(Continued on next page)

(Continued from previous page)

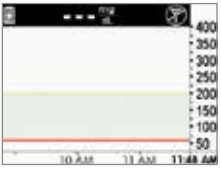
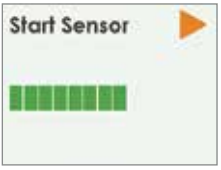
Step	What you see	What you do
4		Locked screen. *Initial calibration* prompt tells you when warmup is complete. Chapter 7 covers calibrating.
5		*Initial calibration* prompt tells you when warmup is complete. Sensor warmup is complete. You're ready to calibrate!

Receiver: Starting a Session

Step	What you see	What you do
1		**Press** *Select* to turn on receiver.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
2		From Trend Graph. **Press** *Select* to go to *Main Menu*.
3		**Press** *Down Arrow* to highlight *Start Sensor*. **Press** *Select* to start new sensor session. **NOTE:** After sensor starts, *Start Sensor* option disappears.
4		"*Start Sensor*" progress bar confirms two hour sensor warmup. Keep your receiver within 20 feet during the warmup period.
5		Receiver returns to the trend graph screen.
6		**Make sure** *receiver* and *transmitter* are communicating. **Check** *receiver* 10 minutes after starting for *Bluetooth* icon. • Solid: Connected • Blinking: Searching for connection • No *Bluetooth* Icon: No connection

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
7		**Wait.** Screen provides countdown of the two hour sensor warmup.
8		Sensor warmup is complete. You're ready to calibrate!

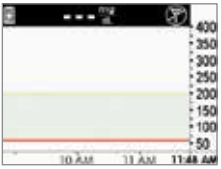
6.9 Receiver *Bluetooth* Tips

Your transmitter and receiver begin communicating once you start a sensor session. After approximately 30 minutes, if the *Bluetooth* symbol is solid, and not blinking, your transmitter and receiver are talking to each other.

- If blinking, *Bluetooth* is looking for your transmitter
  - Make sure your transmitter and receiver are within 20 feet of each other

If the *Bluetooth* icon isn't on the receiver and the Signal Loss icon appears in the receiver's upper right corner of the status bar, they're not communicating.

No Communication Between Transmitter and Receiver

Step	What you see	What you do
1		**Check** correct transmitter SN is in receiver. • SN is on the label on bottom of transmitter box **Press** *Select* to go to *Main Menu*.
2		**Press** *Down Arrow* to *Settings*. **Press** *Select*.
3		**Press** *Down Arrow* to *Transmitter*. **Press** *Select*.
4		**Press** *Select*.

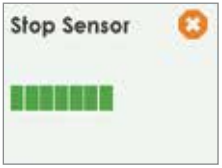
(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
5		**Check** correct transmitter SN is in receiver. • SN is on the label on bottom of transmitter box **Compare** SN in receiver to SN on transmitter box. If correct, call our 24/7 Technical Support department, toll free at **1.877.339.2664** or toll at **1.858.200.0200** for help. **Press** *Select* to exit screen. **Press** *Left Arrow* twice to go to *Main Menu*.
If Wrong SN Entered		
6		**Press** *Left Arrow* twice to go to *Main Menu*.
7		If sensor session has started, to correct transmitter SN, you must stop the sensor session. **Press** *Down Arrow* to *Stop Sensor*. **Press** *Select*.
8		**Press** *Select* to stop session.

(Continued on next page)

(Continued from previous page)

If Wrong SN Entered		
9		**Wait** for sensor session to end.
10		From *Main Menu*: **Press** *Down Arrow* to *Settings*. **Press** *Select*.
11		**Press** *Down Arrow* to *Transmitter*. **Press** *Select*.
12		**Highlight** *Transmitter SN*. **Press** *Select*.
13		**Enter** correct SN using *Up/Down Arrow*. **Press** *Up/Down Arrow* to select and enter transmitter SN. **Press** *Right Arrow* to move to next digit. **Press** *Select* to save and close. **Press** *Left Arrow* twice to return to Main Menu.

(Continued on next page)

(Continued from previous page)

If Wrong SN Entered		
14		Start Sensor Session. **Press** *Up/Down Arrow* to highlight *Start Sensor*. **Press** *Select* on *Start Sensor*.

6.10 Sensor Session Warmup

The sensor takes about two hours to adjust to your body. While you are in the sensor warmup period, you can customize your settings. Chapter 12, steps you through how to personalize your Dexcom G5 Mobile CGM System's display devices.

Once the sensor warmup is complete, you're ready to enter your initial calibrations! The next chapter shows you how.

Summary

Now You Can:

- Identify sensor applicator features
- Properly prepare for sensor insertion
- Choose the best location to insert your sensor
- Correctly insert your sensor
- Prepare transmitter for placement
- Properly attach transmitter to sensor
- Outline sensor warmup
- Identify countdown icon

What's Next?
The next chapter guides you through the calibration steps.

Chapter 7

Let's G5! The Basics:
Calibration

7.1 Introduction

In the previous chapter, you learned how to insert your sensor, transmitter, and start a new sensor session. You're now ready to begin your last step before getting your sensor glucose readings: Calibration.

This chapter reviews not just your initial calibration, but also update calibrations required throughout your sensor session. After this chapter, you will be able to:

- Calibration Overview
  - Define calibration
  - Explain the importance of calibration
  - Identify steps to ensure a successful calibration
- Recognize steps in taking accurate blood glucose measurement
  - Identify the correct blood glucose site for calibrations
  - Prepare finger for fingerstick measurement
- Determine if you should/should not calibrate
  - Recognize when you can enter fingerstick measurement for calibration
  - Recognize when you shouldn't enter the fingerstick measurement for calibration
  - Determine if you need to calibrate outside of the normal calibration requirements
- Initiate startup calibration
- Perform update calibrations
- Correctly enter your fingerstick measurement
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Identify calibration errors

7.2 Calibration Overview

What Is a Calibration?

As you learned earlier, the sensor glucose readings come from measuring the glucose fluids found between your cells (interstitial fluids). Although blood and interstitial fluids are similar, sensor glucose readings can be different between your fingerstick and your CGM. Calibration provides a comparison, or measurement, between your meter's fingerstick measurement and the sensor's glucose readings, allowing alignment between the sensor and meter.

Your BG meter 'teaches' the sensor your glucose values through calibration. Just like a clock can need adjusting – calibrations allow your CGM to adjust to your body.

Why Is Calibrating Important?

Calibrations are a must to make sure the CGM system is performing at its best.

By calibrating when the system notifies you that a calibration is due, the Dexcom G5 Mobile CGM System uses your meter's BG value to make sure the sensor glucose readings remain accurate throughout your session.

How Do I Calibrate?

Take a fingerstick measurement from your meter, and simply enter the meter's BG value into your display device. This chapter lets you know what precautions you need to take before taking your BG meter value, then entering your data. Up to now, you needed to enter information such as Alerts, transmitter SN, etc., separately for the receiver and smart device. Calibration is different.

Don't enter your BG values in both devices, enter into either your app or the receiver. If you enter your meter's BG value into your receiver, it takes about five minutes for your sensor glucose readings to begin. In approximately ten minutes, you can view the readings in the other display device.

How Often Do I Calibrate?

There are three primary "must do" calibration events, each with its own prompts:

1. Two initial calibrations once your warmup session is complete.
2. Update calibrations done twice daily, once every 12 hours.
3. When you're prompted.

If you receive a calibration prompt outside of your scheduled calibration schedule, the system doesn't accept your most recent calibration or your meter's BG value is very different from the sensor's glucose reading.

Don't worry about keeping track of the time between calibrations, the system will prompt you when you are ready for another.

Now you have an overview of calibration, let's review some contraindications, warnings, and precautions you need to know and follow before you calibrate.

7.3 Safety Statements

CONTRAINDICATION

Don't: *Never take any medications containing acetaminophen during your sensor session.*

Why: Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing sensor may falsely raise sensor glucose readings. Level of inaccuracy depends on:

1. Amount of acetaminophen active in your body.
2. May be different for each person.

Consequences: Without correct readings you might miss a severe low event.

WARNING

Don't: *Never use the Dexcom G5 Mobile CGM System sensor glucose readings for treatment decisions.*
Do: *Only use BG values from your BG meter for treatment decisions (e.g., how much insulin to take).*

Why: Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's blood glucose values.

Consequences: Using sensor glucose readings for treatment decisions could result in you missing a severe low or high event.

WARNING

Do: *Calibrate at least once every 12 hours.*

Why: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings.

Consequences: Missing severe low (hypoglycemia) or high (hyperglycemia) Alarm or Alerts.

PRECAUTION

Do: *Look at trend arrows before calibrating. Trend arrows help you determine if you can calibrate now or should wait.*
Don't: *Never calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute.*

Never calibrate when you see:

- *A single arrow, pointing up*
  - *Rising 2-3 mg/dL each minute*
- *Two Arrows pointing up*
  - *Rising more than 3 mg/dL each minute*
- *Single arrow pointing down*
  - *Falling 2-3 mg/dL each minute*
- *Two arrows pointing down*
  - *Falling more than 3 mg/dL each minute*

Why: Calibrating during significant rise/fall of blood glucose may affect accuracy of sensor glucose readings.

Consequences: You may miss a severe low or high glucose event.

PRECAUTION

Do: *Enter the exact BG value displayed on your BG meter within five minutes of a carefully performed fingerstick measurement.*

Why: Entering the wrong blood glucose values, or waiting more than five minutes before entry, might affect sensor accuracy.

Consequences: You may miss a severe low or high glucose events.

PRECAUTION

Do: *Only use fingerstick measurements from your BG meter for calibration.*
Don't: *Never use alternative site blood glucose values such as blood from palms, forearms, etc.*

Why: Alternative site BG values are different from a fingerstick blood glucose value and may not reflect most recent blood glucose value.

Consequences: You may miss a severe low or high glucose event.

7.4 When to Calibrate

Calibrating on a regular schedule aligns your sensor glucose readings with your meter's BG values. Without calibrations, your sensor may be inaccurate, and as a result, so will your display device's sensor glucose readings, Alerts, and prompts, etc.

There are important times when you *must* calibrate:

1. Initial or Start-Up Calibration: two hours after you insert your sensor.
2. 12 Hour Update: every 12 hours after two hour startup calibration.
3. When system prompts you.

With calibration prompts, your sensor and display device helps you keep your calibration schedule on track. If your BG values are not between 40-400 mg/dL, the system won't accept your calibration. Wait until you are within the 40-400 mg/dL range before entering your BG values.

Initial Calibration: Sensor Start-Up Completed

1. At prompts (see next table) enter two back-to-back fingerstick measurements into just one device.
2. No need to do initial calibrations twice.
    a. Calibration data flows between the receiver and your app.
    b. Five minute reporting delay between devices.
3. First update calibration is 12 hours after your initial calibration.

Update Calibration

Update calibrations are typically 12 hours since your last calibration, however it can be sooner. As an example, if you know your next calibration is due at 4 AM, you can do the calibration before bedtime, resetting the 12hour count down.

1. Enter one fingerstick measurement at least every 12 hours.
2. Display devices provides calibration prompts.
3. You may be prompted to enter additional fingerstick measurements as needed.

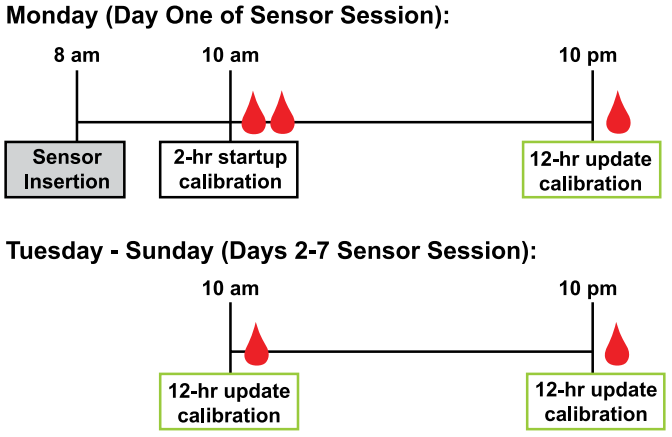


Figure 5. Example Minimum Calibration Schedule During Seven-Day Sensor Session

7.5 Calibration Prompts

Sensor Session Start-Up Calibration Prompts

Once your two hour sensor start-up is complete, your display device tells you it's time to enter the first of your two back-to-back start-up calibrations. Once the system has accepted your BG values, your glucose readings begin. If you don't enter your BG values right away, the system reminds you every 15 minutes. Remember, only use your BG meter for calibrations, and never enter values from your CGM.

Start-Up Calibration Prompts

Device	What you see	What it means	What you do
First Calibration			
Smart Device: Lock Screen		Sensor warmup is complete. Ready for first of two initial calibrations.	Follow steps in Section 7.6 and 7.7. Immediately prepare for next calibration.
Smart Device: In App			
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means	What you do
Second Calibration			
Smart Device: Lock Screen		Sensor accepted first calibration. Ready for second BG meter value.	Follow steps in Section 7.6 and 7.7. Next calibration in 12 hours.
Smart Device: In App			
Receiver			

Your sensor glucose readings begin in approximately five minutes once the device(s) accepts your calibrations.

Update Calibration Prompts

Once your start-up calibration is done, your update calibration schedule begins.

The steps to enter your update calibrations are the same as your initial calibration, including only entering values in one display device. The only difference is, with update calibrations, enter your BG meter value just once.

Like the reminders you received with your initial calibration, if you don't enter your BG meter values right away, the system prompts you every 15 minutes.

Update Calibration Prompts

Device	What you see	What it means	What you do
Smart Device: Lock Screen		Enter update calibration. If prompt doesn't go away: • System didn't accept calibration • BG values are very different from sensor glucose readings	Follow steps in Section 7.6 and 7.7. Immediately prepare for next calibration.
Smart Device: In App			
Receiver			

Tap *message* to clear prompt on your smart device and to clear a prompt on your receiver, **press** *Select*.

Sound/Vibration Prompts

In case you can't look at your screen, both the smart device and receiver provide, with the exception of your regular 12 hour update calibration, beep/vibration prompts to let you know it's time to calibrate or if there was a system calibration error.

For more information on setting your sound/vibration prompts and how to clear them, please see Chapter 9.

Smart Device
Calibration prompts will alert you with a triple beep if your smart device is not on *Silent* or *Do Not Disturb*.

Receiver
The receiver alerts you with an initial vibration for calibration prompts. If not cleared, you receive a vibrate/beep every five minutes until confirmed.

7.6 Preparing for Calibration

Your sensor depends on you to help make its sensor glucose readings accurate. If you don't prepare properly for the calibration, your sensor may not provide you with the most accurate sensor glucose readings.

Eight Steps to Successful Calibration:

Do:

1. Wash and dry your hands before staking a fingerstick measurement.
2. Always use the same meter you routinely use to measure your blood glucose.
    a. Blood glucose meter and strip accuracy vary between meter brands.
    b. Switching within a session might cause sensor glucose readings to be less accurate.
3. Follow meter's instructions exactly when taking your fingerstick measurement.
4. Verify test strips are current and, if required, coded correctly with meter.
5. Check: Is *Bluetooth* is active?
6. Use fingerstick BG values only.
    a. Other sites are not as accurate.
    b. Must enter within five minutes of taking BG meter value.
    c. Enter exact BG value from your meter for each calibration.

Don't:

7. Don't take acetaminophen containing medication during your session (e.g., Tylenol).
    a. See your healthcare professional to better understand how long acetaminophen is active in your body.
8. Don't calibrate if your BG values are under 40 mg/dL or over 400 mg/dL.
    a. If BG value is outside of this range, receiver doesn't understand these values and won't calibrate.
        i. You must wait until your blood glucose is in the range to calibrate.

Be safe—if blood glucose is low, first treat low blood sugar, and then calibrate.

7.7 Ready? Set? Calibrate!

You've followed the eight steps above, have a valid BG value from your meter, and your display device keeps alerting you: Calibrate! Calibrate! Calibrate!

Remember:
You don't have to take a fingerstick measurement for each display device when calibrating, once you enter the reading into one, data is pushed to the other within five minutes.

Next are steps to enter your calibrations using the app, followed by the steps for entering your calibrations into the receiver.

Calibrate With Your Dexcom G5 Mobile App

Step	What you see	What you do	Additional info
1		**Tap** *circle.*	**Initial calibration:** Enter two back-to-back meter BG value. **Update calibration:** Enter one meter BG value.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do	Additional Info
2		**Enter** meter's *BG value* using number pad. **Tap** *Save*.	Double check your numbers. Entering wrong values can affect the sensor's accuracy.
3		**Verify** value is correct. **Tap** *Save*. If not correct: **Tap** *Cancel*. **Reenter** correct value.	

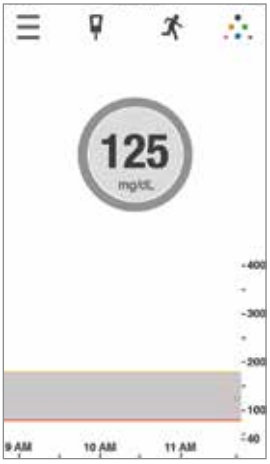
(Continued on next page)

(Continued from previous page)

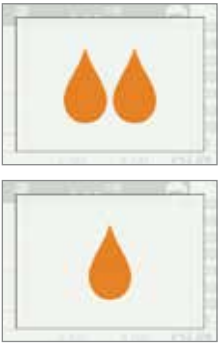
Step	What you see	What you do	Additional Info
4		**Tap** *circle* to enter your second BG value. Follow steps 2-3 and enter second reading.	
5		Meter icon has no calibration prompt. Calibration accepted.	Your calibration was successful.

(Continued on next page)

(Continued from previous page)

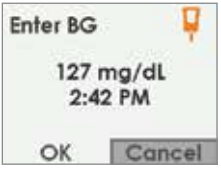
Step	What you see	What you do	Additional Info
6		**Wait** for next calibration prompt in 12 hours.	Default Home Trend screen. Calibration accepted.

Calibrate With Your Dexcom G5 Mobile Receiver

Step	What you see	What you do	Additional Info
1		**Press** *Select* to turn on receiver. **Press** *Select* again for Main Menu.	You won't see calibration prompts when receiver screen is black.

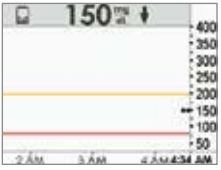
(Continued on next page)

(Continued from previous page)

Step	What you see	What you do	Additional Info
2		**Press** *Up/Down Arrow.* **Highlight** *Enter BG.* **Press** *Select.*	
3		**Press** *Up/Down Arrow* to change numbers. **Stop** at meter's BG value. **Press** *Select.*	Sensor default reading is 120 mg/dL. If sensor glucose reading is within the last 15 minutes, screen will show sensor's actual reading.
4a		Verify BG value is correct. If correct: **Press** *Select.*	If Select is not pressed: • Receiver times out • BG level isn't recorded
4b		Verify BG value is correct. If incorrect: **Press** *Right Arrow* to Cancel. **Press** *Select.* **Reenter** BG value.	Cancel and re-enter BG value. Fingerstick measurement must be within five minute window.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do	Additional Info
5		**Wait**.	"Thinking" screen. BG value is accepted.
6		Immediately take another meter reading. Enter meter's BG Value.	First calibration accepted. Time for second calibration.
7		**Wait** for next calibration prompt in 12 hours.	Default Trend screen. Calibration(s) accepted.

7.8 Calibration Errors

Before or during your calibration process, your display device may show error prompts. If the prompts don't go away after 15 minutes, refer to Chapter 18, Troubleshooting.

Device	What you see	What it means	What you do
Smart Device: In App		Sensor can't calibrate now.	**Wait** 10-15 minutes. **Retake** fingerstick measurement at prompt. **Enter** BG value.
Receiver			
Smart Device: In App		System didn't accept recent calibration.	Additional calibration needed immediately. **Calibrate**. No sensor glucose readings.
Receiver			

Approximately five minutes after entering your second BG meter value, your display device(s) will start providing sensor glucose readings and glucose level trends. While each display device may have different ways of presenting sensor glucose readings and trends, the meanings are the same.

Fingerstick measurements entered into one device will be available in the other approximately ten minutes after entering data.

Summary

Now You Can:

- Calibration Overview
  - Define calibration
  - Explain the importance of calibration
  - Identify steps to ensure a successful calibration
- Recognize the steps required to take an accurate blood glucose levels
  - Identify the best blood glucose site for calibrations
  - Prepare finger for fingerstick measurement
- Determine if you should/should not calibrate
  - Recognize when you can enter BG meter values
  - Recognize when should not enter the BG meter values
  - Determine if you need to calibrate outside of the normal calibration guides
- Initiate startup calibration
- Perform maintenance calibrations
- Correctly enter your fingerstick measurement
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Identify calibration errors

What's Next?

In the next chapter, you'll learn how to end a typical seven day sensor session, what to do if you need to end your sensor session early, along with removing the transmitter and determining if you need to replace it.

Chapter 8

Let's G5! The Basics:

Ending Your Sensor Session and Transmitter Session

8.1 Introduction

Dexcom G5 Mobile Sensor Sessions last seven days. This chapter reviews what you should expect when your session is about to expire, removing the sensor and transmitter. It also covers how to determine if you need to end your session early.

After this chapter, you will be able to:

- Identify replace sensor prompts at the end of a seven day sensor session
- Recognize when you have to end a sensor session early
- Successfully end a sensor session early
    - Identify how you can prevent sensor session failures
- Remove your sensor pod with transmitter attached
- Separate transmitter from sensor pod
- Determine if transmitter can be used for another sensor session

To keep up with your glucose trends, it's important to begin a new sensor session as quickly as possible. After a sensor session ends, the sensor stops taking your sensor glucose readings. You won't get your trends, nor will you get any Alarm or Alerts.

Before stopping a session, and removing the sensor pod and transmitter, review the following safety statements to make sure you don't harm yourself.

8.2 Safety Statements

WARNING

Don't: *If a sensor breaks under the skin with no portion visible above the skin, don't remove it. Don't ignore sensor fractures.*
Do: *Seek professional medical help if you have symptoms of infection or inflammation (e.g., redness, swelling or pain) at the insertion site.*

Always report a broken sensor to our Technical Support, 24/7, team as soon as possible:
Toll free: **1.877.339.2664**
Toll call: **1.858.200.0200**

Why: Sensors may fracture on rare occasions.

Testing done in a controlled environment (in-vitro) didn't find any safety hazards during an MRI with a broken off sensor under the skin. The wire didn't heat up nor have any significant movement during the MRI, images were affected only in the area around the sensor's wire.

MRI with broken wire
If you have experienced a broken sensor and are planning to take an MRI, please discuss the following with your doctor or technician.

Laboratory (in vitro) MRI tests did not detect any safety hazards for a broken sensor that remains in the body.

There was no significant movement or heating of the wire. Imaging artifacts were limited to the area around the wire.

PRECAUTION

Do: *Keep Transmitter until it's battery life has ended.*

Why: Transmitter is reusable.

- Use for multiple sessions

8.3 Ending Your Sensor Session

There are different ways your session might end.

The most common is your sensor's typical seven day timeframe ended. The second is ending the sensor session early. You may end a session early based on a personal decision,

or on rare occasions, the receiver or app detects sensor issues and prompts you to end the session.

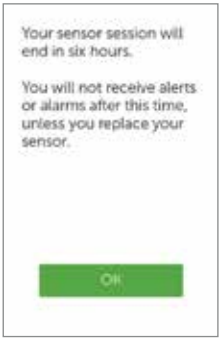
Let's review ending a normal session first, later in this chapter we'll review the prompts for ending the session early.

Ending Your Seven Day Sensor Session

Just like other prompts, your sensor session ending prompts need clearing:

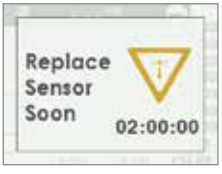
- App
  - **Tap** *screen*
- Receiver
  - **Press** *Select*

Ending Sensor Session Prompts

Device	What you see	What it means
At Six Hours		
Smart Device: Lock Screen		Prompts begin when sensor session has only six hours left. Clock will countdown until session has ended. Continue to get sensor glucose readings.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
At Two Hours		
Smart Device: Lock Screen		Two hours remain on your current sensor session. Continue to get sensor glucose readings.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
At Thirty Minutes		
Smart Device: Lock Screen		Thirty minutes remain. Continue to get sensor glucose readings.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Session Ended		
Smart Device: Lock Screen		Session has ended. **App** **Tap** screen's "?" for steps to: • Remove sensor • Insert new sensor **Receiver** **Press** *Select* to clear.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Session Stopped		
Smart Device: Lock Screen	N/A	Sensor session has stopped. **App** • No sensor glucose readings • Prompts for new session **Receiver** • Straight line ○ No sensor glucose readings
Smart Device: In App		
Receiver		

Sound/Vibration Prompts

In case you can't look at your screen, both the smart device and receiver provide beep/vibration prompts to remind you your sensor session will end in 30 minutes, it has just ended, or if your sensor failed and you need to start a new session. Remember, if your smart device is on Silent or Do Not Disturb, you won't get any sound prompts.

For more information on setting your sound/vibration prompts, please see Chapter 9.

Smart Device
Your smart device prompts you with a triple beep. If not cleared, you receive the triple beep twice, five minutes apart.

Receiver
The receiver alerts you with an initial vibration prompts. If not cleared, you receive a vibrate/beep twice, five minutes apart.

Once a sensor session has expired, you are ready to start your new session! If you're not sure what to do, the app will provide instructions, or you can refer to the Quick Start Guide, online tutorials, or go to Chapter 6 in the User Guide.

Ending Your Sensor Session Early

For personal reasons, you may want to force quit a sensor session early (e.g., you're getting an MRI and need to remove sensor pod).

Or, occasionally, the app or receiver may detect something is wrong with your sensor and let you know it's stopping the current session.

This may be caused by a number of reasons:

1. Unresolved calibration issues.
2. Error symbol does not go away.
3. Wait symbol does not go away.
4. Sensor is coming out of the body (for example, the adhesive is peeling off).

You'll receive error prompts leading to a new sensor session. If you see error prompts, always contact Technical Support before stopping a sensor session early.

Technical Support, 24/7, at:
Toll free: **1.877.339.2664**
Toll call: **1.858.200.0200**

When your display device has system errors, you may not receive any sensor glucose readings and you should not calibrate.

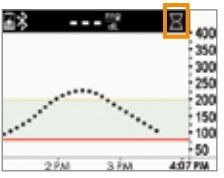
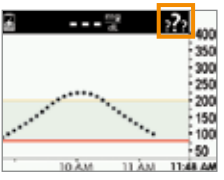
Prompts to End Sensor Session Early

System Prompts

Device	What you see	What it means
Smart Device: Lock Screen		Sensor issues detected. Session ends automatically. No: • Sensor Glucose Readings • Alarm/Alerts Replace sensor.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

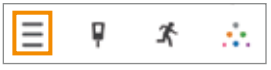
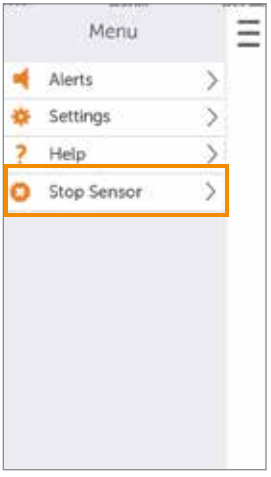
Device	What you see	What it means
Smart Device: Lock Screen		Wait up to three hours while the system autocorrects. Check transmitter—is it properly inserted into sensor pod? Make sure you haven't taken acetaminophen. If not corrected after 3 hours: • Contact Dexcom Technical Support
Smart Device: In App		
Receiver		
Smart Device: Lock Screen		Wait up to three hours while the system autocorrects. Check transmitter—is it properly inserted into sensor pod? Make sure you haven't taken acetaminophen. If not corrected after 3 hours: • Contact Dexcom Technical Support
Smart Device: In App		
Receiver		

The Dexcom G5 Mobile CGM System knows when a typical seven day sensor session is over, automatically ending the session in each display device. However, if you need to end the session early, you need to let the system know by manually stopping the sensor session.

While the end result is the same (ending a sensor session), the steps differ between the app and receiver. If you're using both, no need to stop the sensor session in each: the other display will see the session has stopped.

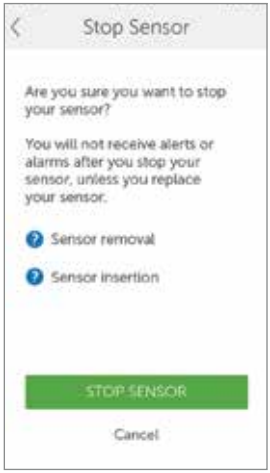
Let's first look at how to end a sensor session in the app, then the receiver.

App: Ending a Sensor Session Early

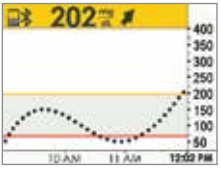
Step	What you see	What it means	What you do
1		Access Main Menu.	**Tap** *Main Menu* icon.
1		Ends sensor session. During session: • *Stop Sensor* option appears Not in active session: • *Start Sensor* option appears	**Tap** *Stop Sensor.*

(Continued on next page)

(Continued from previous page)

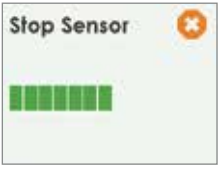
Step	What you see	What it means	What you do
3		Blue "?" icons provide additional information.	**Tap** *Stop Sensor.*
4		Confirms sensor session has ended. Ready for new session.	**Remove** sensor. **Insert** new sensor. **Tap** *green circle* when ready for new session.

Receiver: Ending a Sensor Session Early

Step	What you see	What it means	What you do
1		Go to Main Menu.	**Press** *Select.*

(Continued on next page)

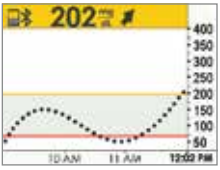
(Continued from previous page)

Step	What you see	What it means	What you do
2		Ends sensor session. During session, *Stop Sensor* option appears.	**Press** *Down Arrow* to *Stop Sensor*. **Press** *Select*.
3		Thinking screen.	**Wait**.
4		Confirms you want to stop sensor. Return to Main Menu.	**Press** *Select*.
5		Ready to start a new session. Not in active session, *Start Sensor* option appears.	**Remove** sensor. **Insert** new sensor. **Press** *Start Sensor* when ready for new session.

Temporary Shutdown Receiver

To save on its battery, you can temporarily shut down the receiver. When shut down, your receiver and transmitter no longer communicate and you will not get any Alarm or Alerts although your sensor session remains active.

Shutting down the receiver does not extend your sensor session past the seven days; it only stops the receiver from communicating with the transmitter. Your sensor session will stop seven days after you started the session.

Step	What you see	What it means	What it means
1		Go to Main Menu.	**Press** *Select*.
2		Ends sensor session. During session, *Stop Sensor* option appears.	**Press** *Down Arrow* to *Stop Sensor*. **Press** *Select*.
3		Confirms you want to shut down. Shuts down receiver.	**Press** *Select*.

Press *Select* to turn the receiver back on. It may take up to 20 seconds for the receiver to turn on.

Preventing Sensor Failures

Sensor failures can happen when your display device doesn't receive your sensor's glucose readings. While it is rare to have a sensor failure, there are preventative steps you can take.

Help prevent sensor failures by checking:

1. Sensor hasn't expired.
2. Transmitter is snapped securely in sensor pod.
3. Sensor pod isn't dislodged or adhesive isn't peeling.
4. Nothing is rubbing against sensor pod (e.g., seat belts, etc.).
5. You selected a good insertion site (see Chapter 6).
6. Insertion site is clean and dry before sensor insertion.

The app and receiver are ready for a new session! However before you can start a new sensor session, you need to end the current sensor session, and remove the old sensor and transmitter.

8.4 Remove Sensor Pod and Transmitter

Remove Sensor Pod

Think of the transmitter as being part of the sensor pod. Do not remove the transmitter before removing the sensor pod from your body.

To remove the sensor pod:

1. Gently peel sensor pod adhesive patch from skin.
    a. Sensor wire comes out with sensor pod.
2. Separate the transmitter from the sensor pod.
3. Discard the sensor pod following your local waste management regulations for disposing blood contacting parts (sensor and applicator).

Remove Transmitter from Sensor Pod

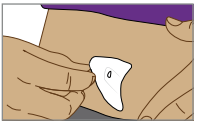
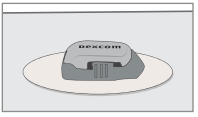
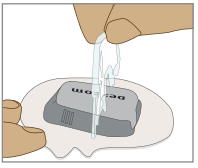
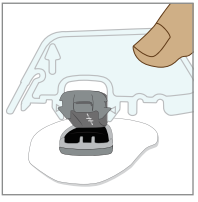
Remember your transmitter is reusable. With a battery life of 90 days, use the same transmitter over a number of sensor sessions. You'll receive prompts as you near the end of its battery life.

Before reusing the transmitter in your new sensor session, separate it from the old sensor pod.

You can detach transmitter two ways:

1. Use safety lock (see With Safety Lock table). You removed this from the applicator barrel at the beginning of the session.
2. Manually spread out tabs holding transmitter in sensor pod (see Without Safety Lock table).

With Safety Lock

Step	Picture	What you do
1		**Grasp** end of *adhesive patch*. **Peel** *adhesive patch* up and away from your body to remove *sensor pod* and *transmitter*.
2		**Put** sensor pod on flat surface.
3		**Place** *safety latch's* jagged edge: • Over transmitters wide edge • In between open slots on sensor pods sides
4		**Lift up** *safety latch*.

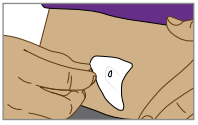
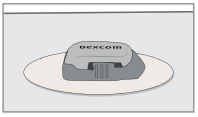
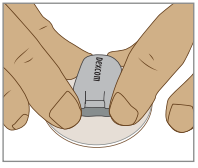
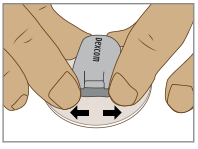
If you no longer have the safety lock, don't worry! You can use your fingers to remove the transmitter from the old sensor pod.

After removing your sensor, and taking the transmitter out of the sensor pod, you're ready to begin a new sensor session. The transmitter's battery is good up to three months. If you haven't received your final seven day transmitter battery life warning, you can reuse the transmitter for your next session.

Remember:

1. Never use same spot repeatedly for sensor insertion.
2. Never use same site for 2 sensor sessions in a row.

Without Safety Lock

Step	Picture	What you do
1		**Grasp** end of *adhesive patch*. **Peel** *adhesive patch* up and away from your body to remove *sensor pod* and *transmitter*.
2		**Put** sensor pod on flat surface.
3		**Grasp** *sensor pod's* wide end with two hands and **place** fingers in side's open slots.
4		**Pull** *tabs* away from transmitter.

8.5 End of Transmitter Battery

How do you know if your transmitter's battery will last through your next session?

System messages help you determine if your transmitter's battery will last through your next seven day session. Starting at three weeks to the end of its battery life, the messages countdown the transmitter's battery until it has only seven days. If the transmitter battery has seven days or less remaining, you won't be able to start a new session.

Transmitter Battery Messages

Device	What you see	What it means
Smart Device: Lock Screen		Battery will expire in three weeks. Check your email for more details.
Smart Device: In App		
Receiver		

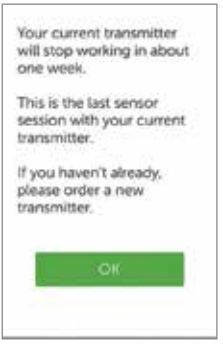
(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Smart Device: Lock Screen		Battery will expire in two weeks. Order a new transmitter.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Smart Device: Lock Screen		Battery will expire in one week. Order a new transmitter.
Smart Device: In App		
Receiver		

To make sure you have a transmitter that's ready for a new sensor session, you may want to reorder a new one at store.dexcom.com, by calling Customer Service (see Section 16.1), or through the channels you used before, at your first low battery prompt.

Sound/Vibration Prompts

In case you can't look at your screen, both the smart device and receiver provide beep/vibration prompts to tell you your transmitters battery is low or the transmitter failed. Remember, if your smart device is turned on to Silent or Do Not Disturb, you won't get any sound prompts.

For more information on setting your sound/vibration prompts and how to clear them, please see Chapter 9.

Smart Device
Your smart device prompts you with a triple beep. If not cleared, you receive the triple beep twice, five minutes apart.

Receiver
The receiver alerts you with an initial vibration prompts. If not cleared, you receive a vibrate/beep twice, five minutes apart.

Summary

Now You Can!

- Identify replace sensor prompts at the end of a seven day sensor session
- Recognize when you have to end a sensor session early
- Successfully end a sensor session early
    - Identify how you can prevent sensor session failures
- Remove your sensor pod with transmitter attached
- Separate transmitter from sensor pod
- Determine if transmitter can be used for another sensor session

What's Next?
Congratulations, you have the basics down!

You can set up your app and receiver, start a sensor session, calibrate, along with ending your sensor session and when to replace your transmitter. But the Dexcom G5 Mobile CGM System can do much more.

In the next part, Part 3: Next Steps, you will learn how to get the most out of your Dexcom G5 Mobile CGM System.

3

NEXT STEPS - GETTING THE MOST OUT OF YOUR DEXCOM CGM

- Reading Trend Graph Screens and Recognizing Trends
- Events
- Alarm and Alerts
- Sounds for Alarm, Alerts and System Messages

Page intentionally left blank

Chapter 9

Next Steps:

Home Screen, Rate of Change Arrows, and Errors

9.1 Introduction to Home Screens

In the previous chapter, you learned about calibrations: why they are important and how to do complete them. Within five minutes of your final calibration your sensor glucose readings begin!

In this chapter, you'll learn three things. First, reading the home screen, second, identifying your sensor glucose readings and trends: What do they mean? What's the best way to use trend information? And third, what you do if you aren't getting your sensor glucose readings.

The purpose of this chapter isn't to tell you how to react to your trends, but to help you recognize where your glucose was and where it's going. Your healthcare professional can help you with your questions on what actions to take based on your glucose trends.

After this chapter, you'll be able to:

- Recognize home screen icons
- Locate sensor glucose reading
- Explain sensor glucose target range
- Recognize the importance of gray, yellow, and red colors
- Identify low/high glucose alert levels on your trend graph
- Describe when you receive a High or Low sensor glucose reading
- Change trend graph views
- Cite differences between rate of change arrows
- Recognize error messages

9.2 Safety Statements

Take a moment and read the safety statements. If not followed, your sensor glucose readings and trends may be less accurate, plus and you may miss important high or low glucose alerts.

CONTRAINDICATION

Don't: *Never take any medications containing acetaminophen during your sensor session.*

Why: Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing sensor may falsely raise sensor glucose readings. Level of inaccuracy depends on:

1. Amount of acetaminophen active in your body.
2. May be different for each person.

Consequences: Without correct readings you might miss a severe low event.

WARNING

Don't: *Never use the Dexcom G5 Mobile CGM System sensor glucose readings for treatment decisions.*
Do: *Only use BG values from your BG meter for treatment decisions (e.g., how much insulin to take).*

Why: Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's blood glucose values.

Consequences: Using sensor glucose readings for treatment decisions could result in you missing a severe low or high event.

WARNING

Don't: *Never ignore symptoms of high and low glucose.*
Do: *Measure your blood glucose with fingerstick measurement if sensor glucose readings don't match your symptoms.*

Why: Your sensor glucose readings may not be accurately reading your glucose.

Consequences: Using sensor glucose readings for treatment decisions could result having severe low (hypoglycemia) or high (hyperglycemia) events.

9.3 Overview of Home Screen

Regardless of your display device, the home screen shows your current sensor glucose value, glucose trend, rate of change arrow and CGM system status. While the screen does look different between the receiver and smart devices, their information and color coding are the same.

No matter how you hold it the receiver's view does not change; the Dexcom G5 Mobile App has two ways to view data based on how you hold your smart device:

1. Vertically in portrait: 3-hour trend information with task bar.
2. Horizontally in landscape: 1, 3, 6, 12 or 24 hour trend information without task bar.

This section first familiarizes you with the app's home screen, then with the receiver's home screen. In other chapters, you'll see how to use the icons or use the navigation wheel to enter data or make system changes.

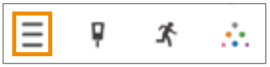
App Home Screen

The app's home screen has two main sections:

1. Status/Task Bar
    a. Status Bar reflects status of smart devices' system.
        i. Battery, *Bluetooth*, etc.
    b. Task Bar allows you to change settings, enter data, etc.
2. Glucose Information
    a. Reflects sensor glucose readings and trends.

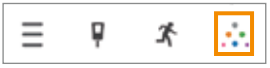
Figure 6. App Home Screen on Mobile Device

Status and Task Bar

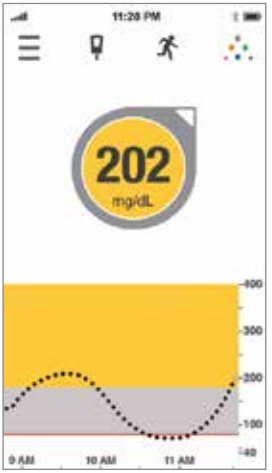
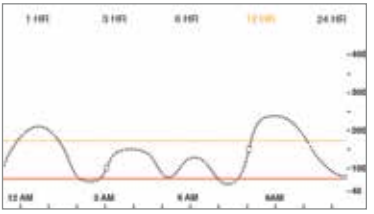
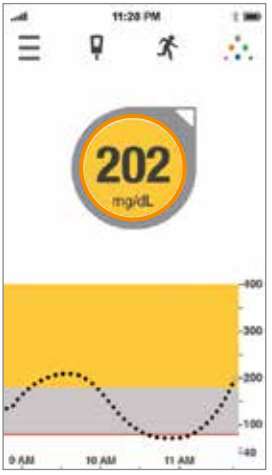
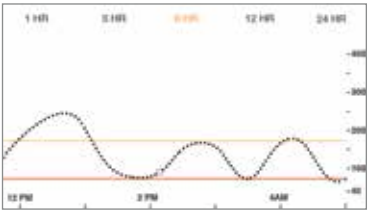
App	Name	What it means	What you do
Status Bar: Information Only			
	Status Bar	Displays signal strength, time, *Bluetooth* and battery level. Changes are made using smart device settings, not in the app. May look different depending on your smart device/carrier.	**Time:** **Check** smart device and receiver show same time. ***Bluetooth:*** **Check** *Bluetooth* is on. **Battery:** App can use up battery—**Check** you are charged.
Task Bar: Complete Tasks			
	Main Menu	Goes to other options.	**Tap** *Main Menu* icon to access: • Alerts • Settings • Help • Start/Stop Sensor
	BG Meter with red circle and number	Calibration Prompt.	**Tap** *icon* and enter fingerstick BG value (see Chapter 7).
	BG Meter without red circle	No need to calibrate.	Do nothing.

(Continued on next page)

(Continued from previous page)

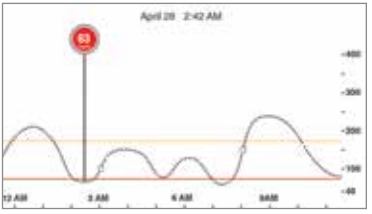
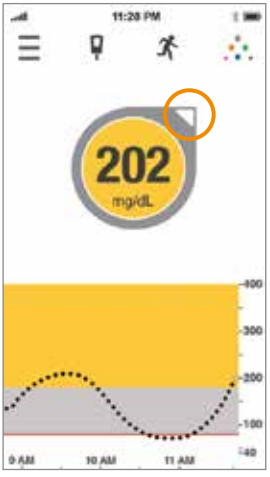
Task Bar: Complete Tasks			
	Event	Enter different events capturing activities affecting your glucose.	**Tap** *icon* to enter data for: • Carbs • Insulin • Exercise • Health (See Chapter 10).
	Dexcom Share	Dexcom Share is only available on the app. Gray icon means Share is not active.	**Tap** *icon* to activate (see Part 5).
	Dexcom Share	Once activated, Dexcom Share icon is colored.	**Do nothing.** **Tap** *icon* to access Dexcom Share.

Glucose Information

App: Portrait	App: Landscape	What it means
		**Home Screen** In Landscape mode, tap on the trend view you want to see at the top of the screen: 1, 3, 6, 12, or 24 historical trend views.
		Number: Most recent sensor glucose reading. Shown in milligrams per deciliter(mg/dL). 1. Yellow: At or above target 2. Gray: Within range 3. Red: At or below target

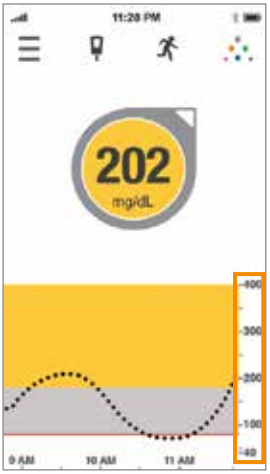
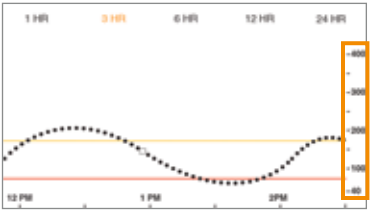
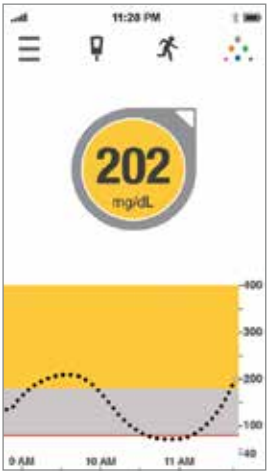
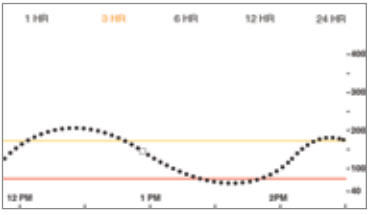
(Continued on next page)

(Continued from previous page)

App: Portrait	App: Landscape	What it means
N/A		**Historical Readings** **Turn** smart device to *Landscape* mode. **Tap** *time*, shows timeframe's sensor glucose reading. **Slide** finger across screen to view rest of day's sensor glucose readings.
	N/A	**Rate of Change Arrow** Direction and number of arrows show sensor glucose change rate.

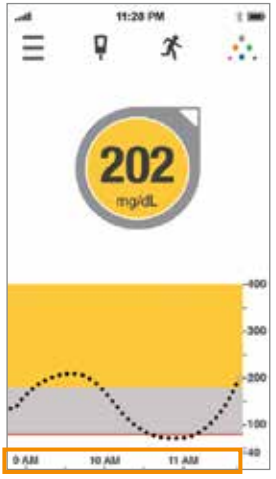
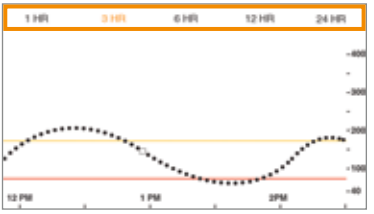
(Continued on next page)

(Continued from previous page)

App: Portrait	App: Landscape	What it means
		**Sensor Glucose Reading Range** Shows between 40-400 mg/dL.
		**Within Glucose Range and Alert Levels** 1. Yellow Bar: High Alert level 2. Gray Background: Within range 3. Red Bar: Low Alert level

(Continued on next page)

(Continued from previous page)

App: Portrait	App: Landscape	What it means
		**Trend Graph Timeframe** Default is most recent 3 hours. **Turn** smart device to *Landscape* mode for most recent 1, 3, 6, 12, and 24 hour readings.

Receiver Home Screen

Unlike your smart device screens, the receiver's screen is not interactive; all prompts are for information only. To make changes or enter data in the receiver, **press** *Select* and go to the Main Menu.

The receiver's home screen has two main sections:

1. Status Bar
    a. Status Bar reflects glucose trends, readings, status of receiver's system (e.g., battery level).
2. Glucose Information Trend Graph
    a. Reflects sensor glucose readings and trends.

This section will get you familiar with the receiver's home screen. In other chapters, you'll see how to use the navigation wheel to enter data or make system changes.

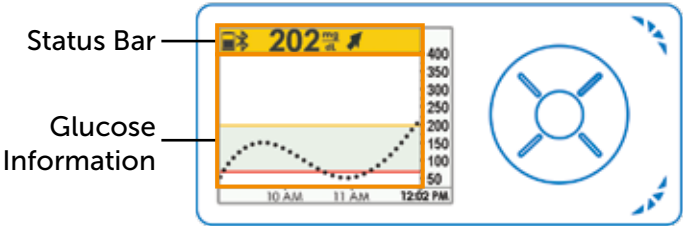
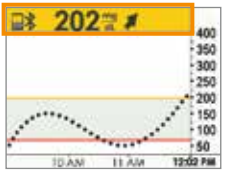
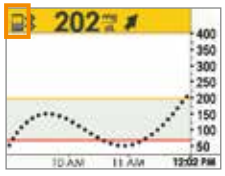
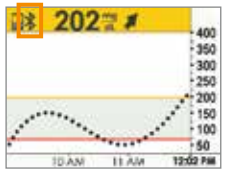


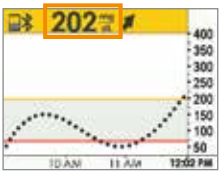
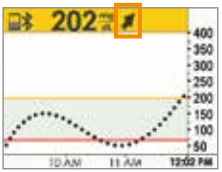
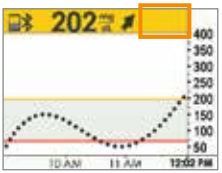
Figure 7. Home Screen on Receiver

Status Bar

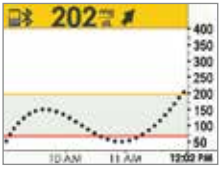
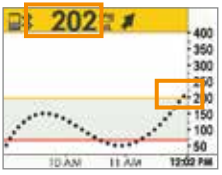
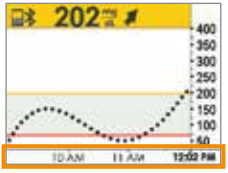
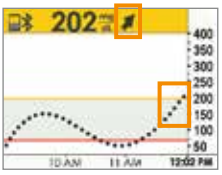
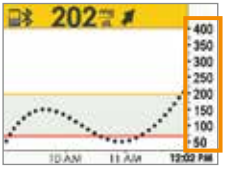
Receiver	Name	What it does	What you do
	Status Bar	Provides at a glance information about the receiver, system, or you. Icons will change based on current data.	Review and take appropriate action.
	Battery	Shows battery level.	When low, **plug** *micro USB cable* into receiver. **Plug** *USB* into the adapter and then into electrical outlet.
	*Bluetooth*	Shows *Bluetooth* connection is working.	Do nothing. Receiver's *Bluetooth* is always on.

(Continued on next page)

(Continued from previous page)

Receiver	Name	What it does	What you do
	Sensor Glucose Reading	Shows most recent sensor glucose reading. Color of status bar changes: • Yellow: At or above target • Gray: Normal range • Red: At or below target	Take appropriate action.
	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value.
	Status Area	Far right. Error icons and calibration prompts.	Take appropriate action.

Glucose Information

Receiver	What it does
	Home screen.
	Number: Most recent sensor glucose reading. Shown in milligrams per deciliter (mg/dL). Color of status bar changes: • Yellow: At or above target • Gray: Normal Within range • Red: At or below target
	**Historical Readings** Default is most recent 3 hours. **Press** *Up/Down Arrows* to access 1, 3, 6, 12, or 24 hour trend views.
	**Rate of Change Arrow** Direction and speed of your glucose changes.
	**Sensor Glucose Reading Range** Shows between 40-400 mg/dL.

(Continued on next page)

(Continued from previous page)

Receiver	What it does
	Glucose target range Alert settings. • Yellow Bar: High Alert setting • Gray Fill: Normal range • Red Bar: Low Alert setting

Now you're familiar with the basic layout of the trend graph screen, can locate readings, identify color coding, and view time frames. Let's take a closer look at the rate of change arrows.

9.4 Rate of Change Arrows

Not sure of how your sensor glucose readings are trending?

Rate of Change Arrows show the speed and direction of your glucose trends based on the last several sensor glucose readings. Arrows and the trend graph help you know when to take action before you are too high or too low.

However, before doing anything, think about your most recent insulin dosing, food intake, overall trend graph, and your current BG value. **Don't overreact to the arrows**. Remember the arrows don't reflect your latest reading: they reflect a combination of recent readings.

Rate of Change Arrows

App	Receiver	What your glucose is doing
		Glucose is steady. Not increasing/decreasing more than 1 mg/dL per minute or up to 15 mg/dL in 15 minutes.
		Glucose slowly rising 1-2 mg/dL each minute or up to 30 mg/dL in 15 minutes.

(Continued on next page)

(Continued from previous page)

App	Receiver	What your glucose is doing
		Glucose rising 2-3 mg/dL each minute or up to 45 mg/dL in 15 minutes.
		Glucose rapidly rising more than 3 mg/dL each minute or more than 45 mg/dL in 15 minutes.
		Glucose is slowly falling 1-2 mg/dL each minute or up to 30 mg/dL in 15 minutes.
		Glucose is falling 2-3 mg/dL each minute or up to 45 mg/dL in 15 minutes.
		Glucose is rapidly falling more than 3 mg/dL each minute or more than 45 mg/dL in 15 minutes.
N/A	No arrow	System can't calculate the speed and direction of your glucose change.

There are a number of reasons why you may not get rate of change arrows:

- You just started your sensor session
- No sensor glucose readings over the last few minutes

9.5 Error Messages

Sometimes the transmitter, or sensor, or display devices aren't communicating, causing you not to get your sensor glucose readings or rate of change arrows. Each device notifies you when there is an issue; however, the notifications look different.

Before the system can move forward, you need to address the error.

App

1. If screen is locked:
    a. Swipe message to go to app.
2. Within app:
    a. Read message.
        i. Tap Question Marks for more information and follow steps as appropriate.

Receiver

1. **Press** *Select* to clear message.

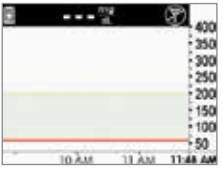
You will not get any sensor glucose readings or rate of change arrows on either display device until the error is resolved. Check with your BG meter to monitor your glucose during these error periods.

Error Messages

What you see		What you do
Bluetooth is Out of Range		
Smart Device: Lock Screen		Make sure there are no obstructions, such as a wall or water between your transmitter and your display device. Move within 20 feet of display device. Wait up to 30 minutes while transmitter restores communication.
Smart Device: In App		
Receiver		

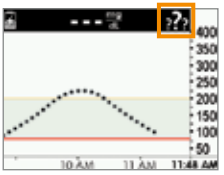
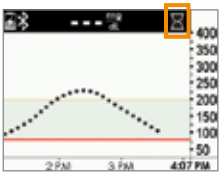
(Continued on next page)

(Continued from previous page)

<table>
<tr><th colspan="3">Bluetooth Off</th></tr>
<tr><td>Smart Device:
Lock Screen</td><td>
</td><td rowspan="3">Smart device:
1. Exit app.
2. Tap Settings.
3. Tap Bluetooth.
4. Turn Bluetooth on.</td></tr>
<tr><td>Smart Device:
In App</td><td>
</td></tr>
<tr><td>Receiver</td><td>N/A; Bluetooth is always on.</td></tr>
<tr><th colspan="3">Not Getting Sensor Glucose Reading</th></tr>
<tr><td>Smart Device:
Lock Screen</td><td>N/A</td><td rowspan="3">Check—Are you:
• Within 20 feet of your display device?
• In your two hour warmup period?
• Outside of your calibration schedule?
• In a sensor session?</td></tr>
<tr><td>Smart Device:
In App</td><td>N/A</td></tr>
<tr><td>Receiver</td><td> 
</td></tr>
</table>

(Continued on next page)

(Continued from previous page)

System Found Temporary Sensor Issue		
Smart Device: Lock Screen	N/A	Don't calibrate. System may correct problem on its own and display sensor glucose readings again. If prompt stays for three hours: Contact Technical Support (see Section 16.1).
Smart Device: In App		
Receiver		
Transmitter and Sensor not Communicating		
Smart Device: Lock Screen	N/A	Wait three hours while the transmitter tries to fix the error. Do not enter calibrations during this time. Make sure your transmitter is properly inserted into the sensor pod. If not corrected: • Contact Technical Support (Section 16.1) • Remove sensor • Insert new sensor
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Calibration Required		
Smart Device: Lock Screen		Error in calibrating. Enter another BG meter value.
Smart Device: In App		
Receiver		
Calibration Error		
Smart Device: Lock Screen	N/A	Wait 15 minutes. Enter a BG meter value.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Display Devices and Transmitter not Communicating		
Smart Device: Lock Screen		Wait 10 minutes. Move display device and transmitter within 20 feet of each other without obstruction (walls or water). Wait up to 30 minutes. In app (if not resolved): 1. **Tap** *Settings*. 2. **Tap** *Bluetooth*. 3. **Turn** *Bluetooth* Off and On.
Smart Device: In App		
Receiver		

If error messages don't go away after you followed necessary steps, and you aren't getting sensor glucose readings, contact Technical Support (see Section 16.1).

Now You Can:

- Recognize home screen icons
- Locate sensor glucose reading
- Explain glucose target range
- Recognize the importance of gray, yellow, and red colors
- Identify low/high alert glucose setting lines
- Describe when you receive a High or Low sensor glucose reading
- Change Trend Graph Hours view
- Cite differences between rate of change arrows
- Recognize error messages

What's Next?

By now you have a pretty good understanding how your trends look on the different display devices, but did you know what you do can affect your trends and patterns? It's important to track actions or well-being, to better understand what you do or how you feel can change your trends.

In the next chapter, you will learn how to enter Events in the Dexcom G5 Mobile System.

Page intentionally left blank

Chapter 10

Next Steps:

Daily Events Affect Your Glucose Trends and Patterns

10.1 Introduction

Your daily activities can impact your glucose trends and patterns. In the previous chapter, you learned how to read your glucose trend screens; in this chapter, you learn how to enter situations, or "Events". By tracking Events, you can determine how certain actions or circumstances affect your glucose levels.

After this chapter, you'll be able to:

- Define Event
- Describe each Event
- Create Events
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Recognize Event markers on the Dexcom G5 Mobile App
  - Describe how Event markers are different in portrait and landscape view
- Describe how to view Events entered via your receiver
- View Event markers on your smart device

10.2 What Is an Event?

Did you take a walk after lunch today? Did you go to happy hour with your co-workers and have a beer? Are you feeling stressed? Did you catch your kid's sniffles? How much insulin did you take for your dinner meal? These are all Events that can raise or lower your blood sugars.

An Event is an action or situation affecting your glucose levels. With the Dexcom G5 Mobile CGM System, you have the ability to enter your daily Events, helping you track their effect on your glucose trends. Once entered into the smart device or receiver, Events can be viewed in Dexcom reports. The reports help you review how each Event influenced your glucose trends.

You can use the reports with your healthcare professional to create a game plan in managing your diabetes.

Even though they differ on how to enter an Event and time, the app and receiver have the same Event categories and subcategories. Later in this chapter, you'll learn how to enter Events in each device.

Event Categories

There are four main Event categories:

1. Carbs
2. Insulin
3. Exercise
4. Health

The fourth category, Health, has more options:

- Illness
- Stress
- Feel High
- Feel Low
- Cycle
- Alcohol

The following table provides more detail on each type of Event.

Events Menu

Device	What you see	What it means	What you do
Carbs			
Smart Device: In App		How many grams did you just eat? Receiver's screen reflects last number entered.	Enter Carb grams per snack or meal, up to 250 grams.
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means	What you do
Insulin			
Smart Device: In App		Receiver's screen reflects last number entered.	Enter insulin units for each dose, up to 250 units. Can't enter type of insulin, only dosage.
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means	What you do
Exercise			
Smart Device: In App		Defaulted at 30 minutes.	Select each exercise's intensity level and duration. Enter intensity and duration. Type of exercise isn't an option.
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means	What you do
Health			
Smart Device: In App		General well being.	Enter different health Events (see following Health Events Menu table).
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means	What you do
Event Time			
Smart Device: In App		Event time.	For each separate Event, enter date/time Event began.
Receiver			

As mentioned in the last table, Health has a series of Events. Tell the system how you are feeling, if you had a drink, if you're having low or high BG symptoms, etc. You select the Event: no amounts are entered, just date and time.

Health Events Menu

Device	What you see	What it means
Health Main Menu		
Smart Device: In App		Use Health Main Menu to access selections.
Receiver		

(Continued on next page)

(Continued from previous page)

<table>
<tr><th>Device</th><th>What you see</th><th>What it means</th></tr>
<tr><td colspan="3">Health Events</td></tr>
<tr><td>Smart Device: In App</td><td>
</td><td rowspan="2">Illness
Have a cold, flu, or any other temporary illness affecting your well-being?
Stress
Are you under stress? Feeling anxious?
High Symptoms
Feel high BG symptoms?
Low Symptoms
Feel low BG symptoms?
Cycle
Have you started your menstrual cycle?
Alcohol
Had a glass of wine, beer, or cocktail?</td></tr>
<tr><td>Receiver</td><td>
</td></tr>
</table>

You can have multiple Events in a single day, or even during the same time frame and enter them all in at the same time. As an example, you're running late because of traffic (Stress) and quickly swing by a drive-thru to get lunch (Carbs of 85 grams).

For your convenience (and safety!), no need to stop everything and enter your Events as they are happening. When you have a moment, you can enter your Events retroactively in your app or receiver.

Events are meant to be entered as individual occurrences: don't enter daily totals, enter each Event separately.

In the next section, you will learn how to enter Events, first in your smart device, then into the receiver.

10.3 Entering Events

You probably will enter Events in your in the display device you use most often; however, you should know how to enter Events into each.

First, let's look at how to enter Events in a smart device, then in the receiver.

When using Dexcom Share, you can allow your Followers see your Event entries. For more Dexcom Share information, please see Part 5.

Enter Events: Smart Device

In the Dexcom G5 Mobile App, Events are just a tap away! The Event icon, a running man, is on the app's home screen's task bar in portrait mode (remember, you don't have the task bar in landscape).

Entering Events for Carbs, Insulin, Exercise, and Health's categories follow the same steps. If you can enter a Carb Event, you can enter an Insulin Event. To enter Events, we'll use the above scenario. The following table shows how to enter Carb (drive-thru lunch) and Stress (traffic jam) Events.

Entering Events: Dexcom G5 Mobile App

Step	What you see	What you do
Enter Carb Event		
1		**Tap** *Running Man.*

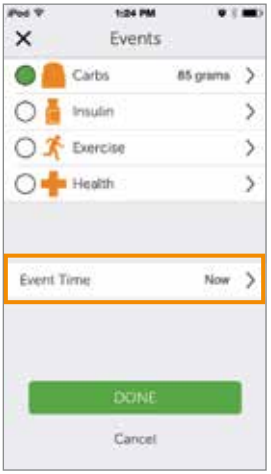
(Continued on next page)

(Continued from previous page)

Enter Carb Event		
2		**Tap** *Carbs*.
3		Add up all carb grams from lunch. **Enter** "85" using keypad. **Tap** *Done*.

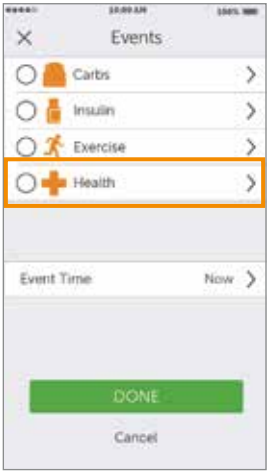
(Continued on next page)

(Continued from previous page)

Enter Carb Event		
4		**Tap** *Event Time*.
5		**Scroll** and **select** date and time. **Tap** *Done*.

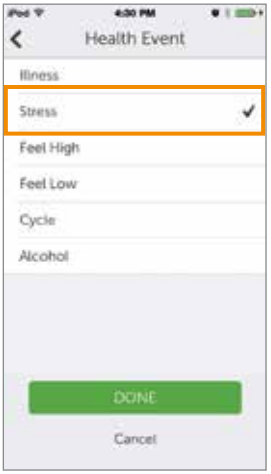
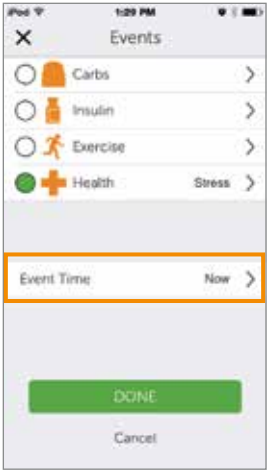
(Continued on next page)

(Continued from previous page)

Enter Carb Event		
6		**Tap** *Save* or *Cancel*.
Enter Stress Event		
7		**Tap** *Running Man*.
8		**Tap** *Health*.

(Continued on next page)

(Continued from previous page)

Enter Stress Event		
9		**Tap** *Stress*. **Tap** *Done*.
10		**Tap** *Event Time*.

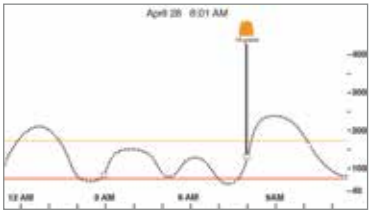
(Continued on next page)

(Continued from previous page)

Enter Stress Event		
11		**Scroll** and **select** date and time. **Tap** *Done*.
12		**Tap** *Save* or *Cancel*.

(Continued on next page)

(Continued from previous page)

Enter Stress Event		
14		**Turn** to landscape.

The receiver and app don't talk to one another. If you enter an Event only into the receiver, while the information will appear on Dexcom reports, you won't get an Event marker on your app's Trend screen.

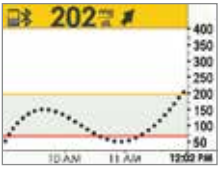
The app has Event markers on its screen, the receiver doesn't.

There may be times when you want or need to enter Events on the Dexcom G5 Mobile Receiver.

Enter Events: Dexcom G5 Mobile Receiver

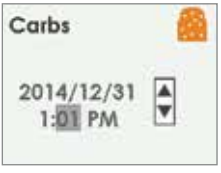
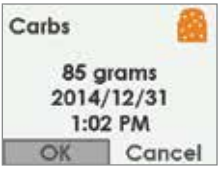
While the Event data is the same between display devices, the flow is not the same, including how to enter the Event's date and time. The following table reviews how to enter the same Carb/Stress Event data from the previous scenario: Carbs at 85, and a Stress Event.

Entering Events: Receiver

Step	What you see	What you do
Enter Carbs Event		
1		Default screen **Press** *Select* to go to Main Menu.

(Continued on next page)

(Continued from previous page)

Enter Carbs Event		
2		**Press** *Down Arrow* until *Events* is highlighted. **Press** *Select*.
3		**Highlight** *Carbs*. **Press** *Select*.
4		Add up all carb grams from lunch. **Arrow** up to “85.” **Press** *Select*.
5		**Press** Left/*Right Arrows* to change time and date. • Left: Backwards • Right: Forward **Press** *Select*.
6		Confirmation screen. **Press** *Select*.

(Continued on next page)

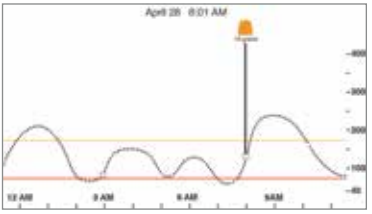
(Continued from previous page)

Enter Health Event		
7		**Press** *Down Arrow* until *Health*.
8		**Press** *Down Arrow* to *Stress*. **Press** *Select*.
9		**Press** *Left/Right Arrows* to change time and date. • Left: Backwards • Right: Forward **Press** *Select*.
10		**Verify** information is correct. **Press** *Left/Right Arrows* to highlight field. **Press** *Up/Down Arrows* to change numbers. **Press** *Select* to save.

10.4 Viewing Events

Events entered into your receiver can only be viewed on a Dexcom report; there are no markers on your receiver's screen.

On your smart device, turn to landscape to view your Event markers. A single small square marks all Events. Slide your finger across the screen or tap the square to get your Event's information.

Landscape	What it does	What you do
	**Landscape Only** Show Event details.	**Landscape Only** • **Tap** *square* • **Slide** finger across screen

Once you have allowed your Share Follower's access to your Trend screen, they too will be able to view your Events. See Part 5 for more information.

Summary

Now You Can:

- Define Event
- Describe each Event
- Create an Event
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Recognize Event Markers on the Dexcom G5 Mobile App
  - Describe how Event Markers are different in portrait and landscape view
- Describe how to view Events entered via your receiver

What's Next?
In the next chapter, you will learn about your trend's Alarm and Alerts helping you monitor you glucose levels. You'll also learn how you know when your system loses its signal and stops communicating.

Page intentionally left blank

Chapter 11

Next Steps:
Sensor Glucose Alarm and Alerts

11.1 Introduction

Monitoring your glucose trends is critical in managing your diabetes. But what happens if you're driving, in a meeting, at the movies, and can't or, don't want to, keep looking at your display device?

Dexcom's G5 Mobile CGM System understands there are times when you can't look at your receiver or smart device; however you still need to know of actionable glucose trends or if you're not getting your sensor glucose readings.

This chapter reviews the sensor glucose Alarm and Alerts based on your sensor glucose readings, allowing you to proactively manage your glucose trend levels and make sure your transmitter is communicating with your display device.

In the next chapter, you'll learn how to customize the Alarm and Alerts.

After this chapter you will be able to:

- Define an Alarm
- Define an Alert
- Identify the different types of Alerts
- Describe the difference between an Alarm and an Alert
- Recognize different Alarm/Alert prompts and sounds
- Determine signal loss is preventing you from getting an Alarm or Alert
- Describe recommended app settings
- Successfully clear an Alert notification
    - Dexcom G5 Mobile App
    - Dexcom G5 Mobile Receiver

Your trending information is one of the greatest benefits of the Dexcom G5 Mobile System. It's important to focus on your trends and rate of change arrows, rather than the exact number of your glucose reading

11.2 Safety Statements

The Alarm and Alerts were designed to keep you safe, helping you avoid severe lows and highs or from missing your readings. The following safety statements help ensure you get your Alerts and Alarm.

WARNING

Do: *Verify your smart device settings let you get Alarm and Alerts.*

To receive Alarm/Alerts you must:

1. **Make sure** Dexcom G5 Mobile App Notifications are **turned on** in *Settings* menu
2. **Verify** app hasn't been shut down.
3. **Adjust** volume so you can hear sounds.
4. **Turn** *Bluetooth* on.
5. **Turn off** *Do Not Disturb.*
6. **Keep** Dexcom G5 Mobile App running in the background.
7. **Restart** app after device is restarted.

Why: Your apps settings do not override phone settings.

Consequences: Missing severe low or high Alarm or Alerts.

WARNING

Don't: *Never assume the Dexcom G5 Mobile CGM System's Alarm/Alert vibrations are different from other vibrating apps.*
Do: *Look at your smart device and check if vibration is a Dexcom G5 Mobile CGM System Alarm or Alert.*

Why: Medical device apps don't have special priority over your smart device's features. You can't determine if the vibration is coming from your Dexcom G5 Mobile App or another app.

Consequences: Missing severe low or high Alarm or Alerts.

WARNING

Do: *Unplug headphones from your smart device when not in use.*

Why: If headphones are plugged in while not being used, you won't hear an Alarm or Alert.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Don't: *Never prevent communication between transmitter and display devices.*
Do: *Keep smart device and receiver within 20 feet of transmitter and away from obstructions.*

Why: If your transmitter display device(s) are more than 20 feet apart or are separated by an obstruction, they might not communicate.

Types of obstruction differ and not all types have been tested. Obstructions can include water, walls, metal, etc.

Water (e.g., swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Do: *Set smart device and receiver settings separately.*

Why: Settings are specific to each display device and don't carry over to other devices. If you set up one device and then use another, you won't get an Alarm or Alert.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Do: *Verify smart device and receiver are turned on.*

Why: Neither the receiver nor smart device will generate sensor glucose readings, Alarm or Alerts if turned off.

Consequences: Missing severe low or high Alarm or Alerts.

11.3 Alarm and Alerts

As part of managing your diabetes, you learned how to read your Trend screen and how to enter Events. In this chapter, you'll learn how Alarm and Alerts can keep you safe from severe lows or highs.

Depending on your display device, you can customize how you receive your Alarm or Alerts.

What Is an Alarm?

While there are a variety of Alerts, *there is just one Alarm*, the Urgent Low Alarm (Alarm) is set at 55 mg/dL. The Alarm will repeat every 5 minutes until you clear the Alarm (see Chapter 12 on how to customize the sounds). If you clear the Alarm and your sensor glucose readings do not go over 55 mg/dL in the next 30 minutes, you get another Alarm.

Unlike Alerts, *the Urgent Low Alarm setting can't be changed or turned off*. Think of it as a safety net: your glucose level is dangerously low—pay attention now!

What Are Alerts?

An Alert is a message telling you your glucose trend levels need attention.

Low/High glucose Alerts tell you when your sensor glucose readings are outside your target glucose ranges. Think of them as an FYI: You need to know what's happening, Rising/Falling Alerts tell you your glucose levels are changing quickly. Their default settings are Off (see Chapter 12 on how to turn them on).

Alerts message you with vibrations (vibrations not available on all smart devices), visual prompts, sounds, or a combination of all three.

Unlike the Alarm, you can customize your different Alert's target range (Chapter 12).

During your initial set up, you establish your low and high alert levels. As mentioned before, this chapter is a review of the Alarm and Alerts, recommended smart device settings and the receiver's default Alert settings.

Chapter 12 will show you how to change their settings: customize glucose levels prompts, how you are notified, and in some cases, how often you get notified. The following are the defaults.

Default Alerts

Low/High Alerts

Your Low/High Alerts have the same color coding as your Trend Graph screen:

1. Red: Glucose levels are below your low threshold.
    a. Default setting of 80 mg/dL.
2. Gray: Glucose levels are within your high/low Alert levels.
    a. No Alerts.
3. Yellow: Glucose levels are above your high threshold.
    a. Default setting of 200 mg/dL.

Rise Rate/Fall Rate/Repeat/Signal Loss Alerts

Rise Rate and Fall Rate Alerts warn you when your glucose levels are changing rapidly, either down or up, and look similar to the rate of change arrows. Repeat Alerts let you know if your sensor glucose readings continue to be above or below your Alert levels.

Glucose Level Alerts

1. Rise Rate
    a. Default setting is Off—No Alert.
    b. Need to change settings to receive Rising Alert.
2. Fall Rate
    a. Default setting is Off—No Alert.
    b. Need to change settings to receive Falling Alert.
3. Repeat
    a. Default setting is Off—No Alert.
    b. Need to change settings to receive Repeat Alert.

Signal Loss Alert

Signal Loss tells you when you and the transmitter are too far from your display device or something is blocking your transmitter signal, causing you not to get sensor glucose readings. The default setting for Signal Loss is On.

Now you have the basics for Dexcom's G5 Mobile's Alarm/Alerts feature. Next, you will learn about each Alarm/Alert in more detail.

11.4 Alarm and Alerts Screens

When you fall within an Alarm or Alert target range, your display device tells you. As mentioned in previous chapters you won't get any Alarm or Alerts within five minutes of calibration.

Let's first review how the information is presented visually across the devices. While the Alarm/Alerts prompts look different on the display devices, they reflect the same information.

After prompts we'll separately review the vibration and audible Alarm/Alerts for app and receiver.

Alarm and Alerts look different based on your display device, but reflect the same information.

Urgent Low Glucose Alarm

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose reading at or below 55 mg/dL. Shows last glucose value. Arrows reflect rate of change. Check BG meter to make treatment decisions.
Smart Device: In App		
Receiver		

Low/High Glucose Alerts

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose reading at or below your low Alert level. Shows most current sensor glucose reading. Arrows reflect rate of change. Can be set to repeat between 15 minutes to 4 hours. Check your BG meter to make any treatment decisions.
Smart Device: In App		
Receiver		

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose reading at or above your high Alert level. Shows most current sensor glucose reading. Arrows reflect rate of change. Can be set to repeat between 15 minutes to 4 hours. Check BG meter to make treatment decisions.
Smart Device: In App		
Receiver		

Rise Rate/Fall Rate Alerts

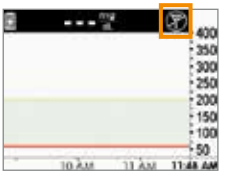
Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose readings rising quickly. Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min). Check BG meter to make any treatment decisions.
Smart Device: In App	 	
Receiver	 	

(Continued on next page)

(Continued from previous page)

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose readings falling quickly. Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min). Check BG meter to make any treatment decisions.
Smart Device: In App	 	
Receiver	 	

Signal Loss Alert

Device	What you see	What it means
Smart Device: Lock Screen		Your receiver and transmitter are not communicating. You will not receive Alarm/Alerts. Check BG meter to check your glucose and make any treatment decisions.
Smart Device: In App		
Receiver		

11.5 App: Alarm/Alert Recommended Settings

The receiver is a stand-alone medical device and used solely to monitor your glucose trends.

The app cannot override the smart devices general settings.

The app can't override your smart device settings:

- When your smart device is on Silent, you'll still receive Alarms and Alerts visual prompts and messages, but not vibrations if you haven't adjusted your smart device settings
- Some smart devices don't have a Vibration feature, so you won't get any vibration notifications
- When your ringer's volume is low, you may not hear an Alarm or Alert
- When your smart device is in Do Not Disturb mode, you won't receive any Alarm/Alerts. The Dexcom G5 Mobile App can't override the Do Not Disturb setting
- If you don't enable your Dexcom G5 Mobile push Notifications settings during set up, you won't get any Alarm/Alerts
- Check in Settings under Notifications on how your Alarm/Alerts are prioritized

For information on smart device settings, see your smart device's instructions.

If you are concerned about missing an Alarm or Alert (e.g., due to smart device settings, app shutting off due to lack of storage, low smart device battery, etc.), bring your receiver with you.

11.6 Receiver: Default Beeps and Vibrations

The Dexcom G5 Mobile Receiver's Alarm/Alerts are vibrations and a beep, or a series of beeps, based on the Alarm or Alert. Beeps and vibrations are preprogrammed into the receiver, and unlike the smart device, the volume can't be changed.

In Chapter 12 you'll learn how to adjust the volume and intensity of your Alarm/Alerts.

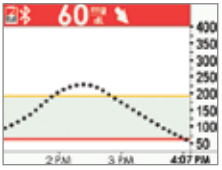
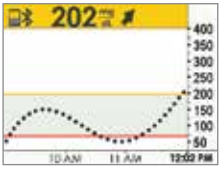
The following is a table of the receiver's default beep and vibration patterns. If you clear the Alert's initial vibration, you won't get any beeps or sounds unless you've turned on the Repeat Alert.

In the next section, you'll learn how to clear the Alarm/Alerts.

Urgent Low Glucose Alarm

What you see	Beeps and vibration
	Initial Default Alert: Vibrates 4x's. **After 5 Minutes:** Vibrates/beeps 4x's every 5 minutes until cleared or sensor glucose readings go above Alarm level. **After 30 Minutes:** After clearing Alarm, continues to notify if sensor glucose readings remain at or below Alarm level.

Low/High Glucose Alerts

What you see	Beeps and vibration
  	**Initial Default Alert:** Vibrates 3x's. **After 5 Minutes:** Vibrates/beeps 3x's every 5 minutes until cleared. Trend screen will continue to reflect Alert until sensor glucose readings go above Alert level.
  	**Initial Default Alert:** Vibrates 2x's. **After 5 Minutes:** Vibrates/beeps 2x's every 5 minutes until cleared. Trend screen will continue to reflect Alert until sensor glucose readings go below Alert level.

Rise Rate/Fall Rate Alerts

What you see	Beeps and vibration
 	Initial Default Alert: None/Off. **After Setting Change:** Vibrates 2x's, 2 sounds. **After 5 Minutes:** Vibrates/beeps 2x's every 5 minutes until cleared.
 	Initial Default Alert: None/Off. **After Setting Change:** Vibrates 3x's. **After 5 Minutes:** Vibrates/beeps 3x's every 5 minutes until cleared or sensor glucose reading drops below Alert level.

Low Repeat/High Repeat

What you see	Beeps and vibration
	Initial Default Alert: None/Off. **After Setting Change:** Vibrates 3x's. **After 5 Minutes:** Vibrates/beeps 3x's every 5 minutes until cleared. Will re-alert if sensor glucose readings drop at or below 55 mg/dL.
	Initial Default Alert: None/Off. **After Setting Change:** Vibrates 2x's. **After 5 Minutes:** Vibrates/beeps 2x's every 5 minutes until cleared.

Signal Loss Alert

What you see	Beeps and vibration
	Initial Default Alert: On. **After Setting Change:** Vibrates 1x. **After 5 Minutes:** Vibrates/beeps 1x every 5 minutes for a total of 6 times if not cleared. After 6 times it will not alert again.

11.7 Clearing Alarm/Alerts

Alerts require you to acknowledge and clear them. How this is done depends on your display device. If using both display devices, you'll need to clear each separately.

Due to their medical importance, the Alarm is more persistent. Even after acknowledging and clearing an Alarm, if your sensor's glucose readings remain at or below 55 mg/dL, an Alarm will sound every 30 minutes until readings are above 55 mg/dL.

Clearing Your Smart Device

Device	What you see	What you do
Smart Device: Lock Screen		**Slide** *Alarm* or *Alert* to access app.
Smart Device: In App		**Tap** *OK* to accept Alarm or Alert.

Clearing Your Receiver

What you see	What you do
	Press *Select*.

Once cleared, you won't receive the same Alert unless you hit the Alert's target range again. Your Alarm will repeat even after clearing if your glucose levels do not return to your target range.

Summary

Now You Can:

- Define an Alarm
- Define an Alert
- Identify the different types of Alerts
- Describe the difference between an Alarm and an Alert
- Recognize different Alarm/Alert prompts and sounds
- Determine if signal loss is preventing you from getting an Alarm/Alert
- Describe recommended app settings
- Successfully clear an Alert notification
    - Dexcom G5 Mobile App
    - Dexcom G5 Mobile Receiver

What's Next?
Up to now, you have learned about the Alarm or Alert default settings. But what do you do if you want to decrease the High Alert glucose level threshold, or you want to continue getting a Low Alert notification if your glucose levels don't improve, even though you cleared the message?

How do you make your Alarm/Alerts fit your needs?

Page intentionally left blank

Chapter 12

Next Steps:

On the Go With G5: Customizing Your Alarm and Alerts

12.1 Introduction

The receiver and app come with default glucose Alert level settings, but perhaps they don't reflect the glucose level that works best for you.

Perhaps you're in a meeting and can only clear an Alert, yet want to make sure your Alert repeats, or continues, until you're able to take corrective measures. Maybe you'd like to get a Rising/Falling glucose Alert, but their settings are off by default. How do you turn them on?

In this chapter, you'll learn how to personalize your Alarm and Alerts tones and glucose levels.

Afterwards, you will be able to:

- Customize your Low/High Alerts
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Adjust Alarm sound notification
- Use receiver's Advanced Alerts
  - Low/High Repeat
  - Rise/Fall Alerts
  - Signal Loss

Each display device has customization options; however the setup flow is different. Before making any changes to your Alert levels, talk with your healthcare professional.

First, let's take a look at personalizing your app Alarm and Alerts, and then we'll review the same process for the receiver.

12.2 Safety Statement

WARNING

Do: *If using both receiver and app for to get an Alarm or Alert, change settings in each display device.*

Why: Any changes to the G5 Mobile app will not carry over to the receiver.

Consequences: Missing severe low or high Alarm or Alerts.

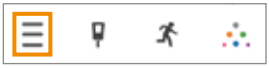
12.3 Changing App Alarm and Alerts

App Screen Overview

The Alerts Main Menu lists all customizable Alerts and Alarm and their current settings. Part of your initial set up included setting your Low/High Alerts. In this chapter, you'll learn how to change them.

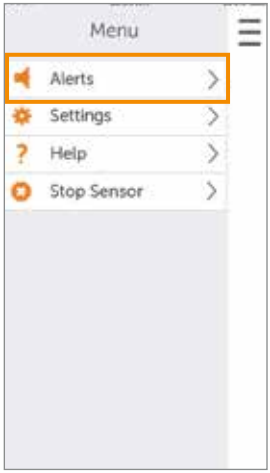
Before learning how to change your settings, let's review the app's Alerts Main Menu screen.

Customizing Alerts: App Alarm/Alerts Screen Overview

Step	What you see	What it means	What you do
1		Access Main Menu.	**Tap** *Main Menu* icon.

(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
2		Access Alerts Main Menu.	**Tap** *Alerts*.
3		All customizable Alarm and Alerts. Current Alert settings. All alerts have: • *On/Off* switch • *Notify me* options • *Sound* options	**Tap** *Alarm/Alert* you want to change.

(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
4		"?" explains: • Each Alarm/Alert Message options • Recommended settings	**Tap** *"?"* for Alarm/Alert information.
5		Urgent Low Glucose Alarm: • Preset at 55 mg/dL and cannot be changed • *Repeat* preset at 30 minutes and can't be changed • *Sound* is the only change option	**Tap** *Sound* to change sound.

Steps to Customize App Alarm/Alerts

Although the results will vary depending on what Alarm or Alert you are customizing, the steps to change your Alarm or Alert are the same:

From app's Main Menu:

1. Tap *Alerts*.
2. Tap the *Alert* you want.
    a. Tap *On* or *Off* switch to turn on desired Alerts.
3. Tap *Notify me*.
    a. Change the Alert glucose level (mg/dL).
        i. Scroll selection wheel, find your desired Alert level.
        ii. Tap to highlight.
        iii. Tap *Save*.
4. Tap *Repeat*.
    a. Change the amount of time you want between your High/Low Alerts if your sensor glucose readings continue to be low or high.
        i. Scroll selection wheel, find your desired Alert level.
        ii. Tap to highlight.
        iii. Tap *Save*.
5. Tap *Sound*.
    a. Assign a different sound to each Alarm or Alert.
        i. Scroll selection wheel, find your desired sound.
        ii. Tap to highlight.
        iii. Tap *back arrow*.

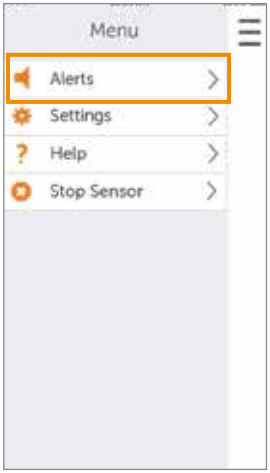
In this following example, we'll change the High Alert level from 200 mg/dL to 190 mg/dL, repeating every hour if you continue to stay high, with a Door Bell sound.

Customizing Alerts: App

Step	What you see	What it means	What you do
Access Alerts' Main Menu			
1		Access Main Menu.	**Tap** *Main Menu* icon.

(Continued on next page)

(Continued from previous page)

Access Alerts' Main Menu			
2		Access Alerts Main Menu.	**Tap** *Alerts*.

(Continued on next page)

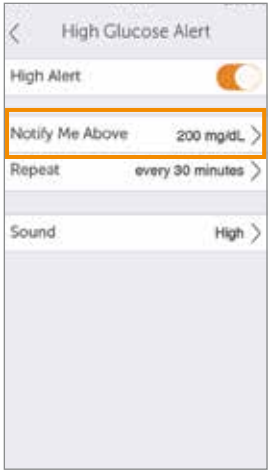
(Continued from previous page)

Changing an Alert

3		Access High Alert settings (mg/dL).	**Tap** *High mg/dL*.
4		Shows High Alert options and current settings.	**Check** *High Alerts* is On. • On - Orange • Off - Gray

(Continued on next page)

(Continued from previous page)

Changing an Alert			
5		Won't get Alerts if Off.	If Off: *On* **Slide** to On. • On - Orange • Off - Gray
6		Change High Alert (mg/dL).	**Tap** *Notify Me Above*.

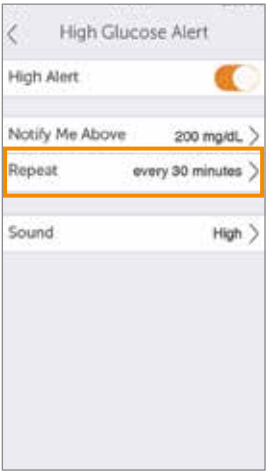
(Continued on next page)

(Continued from previous page)

Changing an Alert			
7		Change glucose level from current level (mg/dL).	**Scroll** selection wheel. **Stop** at 190.
8		Saves new High Alert glucose level (mg/dL). Returns to *High Glucose Alert* screen options. *Notify Me Above* set at 190 mg/dL.	**Tap** *Save*.

(Continued on next page)

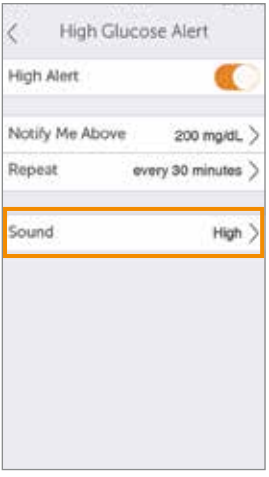
(Continued from previous page)

Changing an Alert			
9		Changes how often your High Alert repeats after initial Alert and confirmation. Repeats only if you are above your high glucose level.	**Tap** *Repeat*.
10		Changing the current repeat setting. Can select in five minute steps (range 15 minutes-4 hours).	**Scroll** selection wheel. **Stop** at 1 hour.

(Continued on next page)

(Continued from previous page)

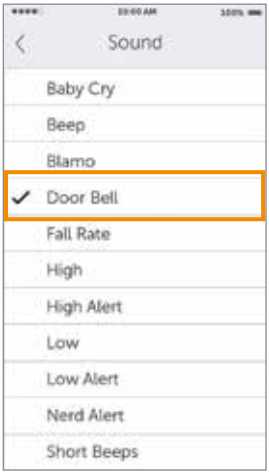
Changing an Alert

11		Saves your new repeat timing. Returns to *High Glucose Alert* screen options. *Repeat* shows how often you'll get notified.	**Tap** *Save*.
12		Customize Alert sound.	**Tap** *Sound*.

(Continued on next page)

(Continued from previous page)

Changing an Alert

13		Changes current sound setting.	**Tap** *Doorbell*. **Tap** *Sound* again to hear sound sample.
14		Saves your new Alert sound. Return to High Glucose Alert Menu.	**Tap** *Back Arrow*.

(Continued on next page)

(Continued from previous page)

Changing an Alert

15		Return to Main Menu.	**Tap** *"X"*.
16		Return to trend screen.	**Tap** *Menu* icon Or **Swipe** right.

Any changes to the app will not carry over to the receiver. If using both, make the same changes in the receiver you made in your smart device. If you don't, you may miss an Alarm or Alert.

12.4 Changing Receiver Alarm and Alerts

You'll notice a flow difference between the app and the receiver when personalizing your Alarm/Alerts. With the app, all Alert adjustments are made from one screen, whereas in the receiver, you make changes in different screens.

Unlike the app, you change your receiver's tones (known as Profiles) through a number of different screens in the Profiles menu.

Profiles

Profiles determine the sound and volume of your Alarm and Alerts.

As mentioned in the previous chapter, the receiver uses a series of beeps/vibrations for an Alarm or Alert. The receiver doesn't have the same variety of tones as the app; however you can adjust their volume. While the receiver doesn't have a silent mode, selecting *Vibrate* will replace audible beeps with quiet vibrations. The only exception is the Alarm: the urgent low Alarm can't be turned off.

Changes made in *Profiles* are applied to all of the receiver's Alarm/Alerts. If you choose *Soft* (see next table), all Alerts are in Soft mode. In Chapter 10, you learned how many beeps each Alarm/Alert has.

Normal is the default setting for your receiver sound Profiles.

Attentive uses a rising or falling melody instead of beeps.

The receiver first vibrates when sending you an Alarm or Alert. If you clear the alert at the first vibration by pressing the *Select* button on your navigation wheel, you won't get any Alarm/Alert tones. If you would like to continue to get your Alarm or Alert after clearing, later in this chapter you'll learn about setting up Repeat Alerts.

HypoRepeat is very similar to the *Normal* Profile, but keeps repeating the fixed low alarm every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm by pressing the *Select* button.

The next table lists the different sound Profiles, starting with the quietest, working its way up to the loudest.

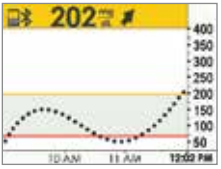
Alarm/Alert Sound Profiles

Icon	Profile name	Notification description
	Vibrate	Vibration only. Only sound is your receiver vibrating. Vibrate is not available for the Alarm.
	Soft	Lower volume beeps.
	Normal	Medium volume beeps. Default Profile.
	Attentive	No beeps. • Rising melody for High and Rising Alerts • Dropping melody for Low and Falling Alerts
	HypoRepeat	Medium volume beeps. Urgent low Alarm only. Repeats fixed low alarm every 5 seconds until sensor glucose reading rises above 55 mg/dL or is confirmed.
	Try It	Sample *Profile* setting before selecting.

After choosing your sound profile, changing it is just a few steps away! Change your *Profile* throughout the day depending on what lays ahead: In a meeting? Select *Vibrate*. Going to a ball game after work? Select *Attentive*.

The next table shows how to change a sound Profile, then sample how it sounds.

Customizing Sound Profiles: Receiver

Step	What you see	What it means	What you do
1		Go to Main Menu.	**Press** *Select*.
2		Second Main Menu screen.	**Press** *Down Arrow*. *Profiles* on second screen.
3		Profiles adjusts volume of Alarm/Alerts.	**Press** *Up/Down Arrow*. **Stop** at *Profiles*. **Press** *Select*.
4		Choose sound *Profile*.	**Press** *Up/Down Arrow*. **Stop** at desired *Profile*. **Press** *Select*.

(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
5		Selected *Profile* check marked.	Sample sound: **Press** *Down Arrow.* **Stop** at *Try It.* **Press** *Select* to have the sound play. Exit Profiles: **Press** *Left Arrow.*
6	N/A	Repeat as needed.	**Repeat** steps 2-5 to change Profile. To Exit: **Press** *Left Arrow* to *Main Menu.*

Profiles allow you to change your Alarm and Alerts tones. The Alerts menu gives you options for personalizing your glucose level Alerts, repeating Alerts, turning your Rising/Falling Alerts on and turning on your Signal Loss Alert.

Alerts Main Menu

Low/High Alert option lets you adjust your low/high glucose Alert level (mg/dL).

Advanced gives you options to turn on Low/High Repeat, Rise/Fall Alerts and Signal Loss Alert.

Low/High Repeat

In the previous chapter, you learned clearing an Alert stops it from repeating. If you want to continue to be re-alerted until your glucose levels are back in your target range, turn on the *Repeat* option.

Rise/Fall Rate

Your trend screen provides visual cues letting you know your sensor glucose readings are falling or rising rapidly.

Constantly looking at your screen may not be practical. You can customize your Rise/Fall Alert with vibrations or beeps letting you know when your glucose is rising or falling (2 mg/dL/min or 30 mg/dL up or down in 15 minutes) or rising or falling rapidly (3 or more mg/dL/min or 45 mg/dL or more up or down in 15 minutes).

The default setting for Repeat and Rise/Fall Rate is *Off*.

It's important you discuss your alert settings with your healthcare professional.

Signal Loss

Signal Loss Alert tells you when your transmitter and receiver aren't communicating. Set the Signal Loss and get alerted if your sensor glucose readings have stopped due to a signal loss anywhere from 20 to 200 minutes.

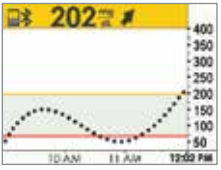
The default setting for Signal Loss is *On*.

Steps to Customize Receiver Alarm/Alerts

Using the same example from changing your app Alerts, let's change the receiver's High Alert notification level from 200 mg/dL to 190 mg/dL, repeating every 60 minutes.

Follow the same steps turning on the Rise/Fall Alerts, and adjusting your Low Alerts.

Customizing Alerts: Receiver

Step	What you see	What it means	What you do
Change High Alert Level			
1		Go to Main Menu.	**Press** *Select*.

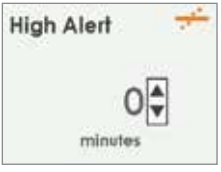
(Continued on next page)

(Continued from previous page)

Change High Alert Level			
2		Alerts option from the Main Menu.	**Press** *Down Arrow.* **Stop** *at Alerts.*
3		Enter Alerts menu option.	**Press** *Select.*
4		Alerts' option menu. Lists different Alerts: High/Low/Advanced (Repeat, Rise/Fall, Signal Loss) Alerts.	**Press** Up/*Down Arrow.* **Stop** at *High Alert.* **Press** *Select.*
5		Alert's current settings. Change your current High Alert level.	**Press** *Down Arrow.* **Stop** at *Level.* **Press** *Select.*
6		Current setting. **Use** *Up/Down* arrows to change your High Alert level (mg/dL).	**Press** *Down Arrow.* **Stop** at 190 mg/dL.

(Continued on next page)

(Continued from previous page)

Change High Alert Level			
7		Saves new High Alert level. Return to Alerts Menu.	**Press** *Select*. To exit: **Press** *Left Arrow*.
Turn Repeart On			
8		Alerts Menu. Choose Advanced to get to Repeat Alert.	**Press** *Down Arrow*. **Stop** *at Advanced*.
9		Enter Advanced Alert options.	**Press** *Select* on *Advanced*.
10		Main Advanced screen. Set Repeat Alerts. Turn On Rise/Fall Rate Alerts.	**Arrow** to *High Repeat*. **Press** *Select*.
11		Initial screen shows current repeat minutes. Change time frame in 5 minute increments.	**Press** *Up/Down Arrow*. **Stop** at 60 minutes.

(Continued on next page)

(Continued from previous page)

Turn Repeat On			
12		Changed *Repeat* time for High Alert.	**Press** *Select*.
13		Changed completed. Return to *Alerts Menu*.	To exit: **Press** *Left Arrow*.

It doesn't matter which device you first use to customize your Alarm/Alert settings, key is making sure you make the same changes in both or you may miss an Alarm or Alert.

Summary

Now You Can:

- Customize your glucose trend Low/High level notifications
  - Dexcom G5 Mobile App
  - Dexcom G5 Mobile Receiver
- Adjust Alarm tones
- Set up receiver's Advanced Alerts
  - Low/High Repeat
  - Rise/Fall Rate
  - Signal Loss

What's Next?

Believe it or not, you are becoming a pro at using your Dexcom G5 Mobile CGM System! You've set up the app and receiver, started a session, calibrated, followed your glucose trends, paid attention to your Alarm/Alerts, prompts, and ended a session!

The next chapters begin our fourth part of the user guide: information you need to know, but unlike the previous chapters, typically not part of your day-to-day Dexcom G5 Mobile CGM System experience.

The next part, Part 4: Everything Else G5, reviews the technical specifications, the warranty, how to take care of the Dexcom G5 Mobile components, going through security when traveling, contacting the Help Desk, Troubleshooting information, and symbols on system components and packages.

4

EVERYTHING ELSE G5

- Warranty
- Maintenance
- Travel Tips
- Customer Service Contacts
- Technical Information
- Troubleshooting
- Package Symbols

Page intentionally left blank

Chapter 13

Everything Else G5:
Warranty: The Fine Print

13.1 Introduction

Sometimes stuff happens. Dexcom has you covered!

The following is our warranty information outlining what we do cover, what we don't and for how long. First the receiver's limited warranty information, then the transmitter's limited warranty information.

13.2 Receiver Warranty Information

Dexcom G5 Mobile CGM System's Limited Warranty

What's Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser ("you" or "Purchaser") that the Dexcom G5 Mobile Receiver (the "Receiver") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period starting from the shipment date and continuing for a year following the shipment date ("Warranty Period"):

Dexcom G5 Mobile Receiver: **1 year** from shipment date

NOTE: If you received this Receiver as a replacement for an in-warranty Receiver, the Limited Warranty for the original Receiver shall continue for the Warranty Period on the original Receiver, but the replacement is not subject to any other warranty.

What's Not Covered?

This Limited Warranty is based on the Purchaser properly using the CGM system in accordance with the documentation provided by Dexcom. You are not permitted to use the CGM system otherwise. You understand that misusing the CGM system, improperly accessing it or the information it processes and transmits, "jailbreaking" your CGM system or cell phone, and taking other unauthorized actions may put you at risk, cause the CGM system to malfunction, is not permitted and voids your Limited Warranty.

This Limited Warranty does not cover:

1. Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
2. Equipment with the ID number removed or made illegible.
3. All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
4. Malfunctions resulting from the use of the Receiver in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
5. Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
6. Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
7. Equipment which has been taken apart physically or which has had any of its software accessed in any unauthorized manner.
8. Water damage to the Receiver.
    a. Receiver is not water resistant.
    b. Do not get the receiver wet at any time.

Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to purchaser, any defective Dexcom G5 Mobile Receiver.

To return, you must send the Receiver to an authorized Dexcom Technical Support Department. Make sure you package the Receiver adequately for shipping.

The return package needs to include:

1. Receiver
2. Sales receipt or comparable substitute proof of sale showing the date of purchase
3. Receiver's Serial Number
4. Seller's name and address

Call Dexcom Technical Support Department for delivery information help:

- Toll free: **1.877.339.2664**
- Charges may apply: **1.858.200.0200**

Upon receipt, Dexcom will promptly replace the defective Receiver.

If Dexcom determines the Receiver isn't covered by this Limited Warranty, Purchaser must pay all shipping charges for the Receiver's return by Dexcom.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the Receiver, and in lieu of all other warranties, expressed or implied, either in fact or by operation of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G5 Mobile CGM System or any feature or service provided by Dexcom for use with the Dexcom G5 Mobile CGM System.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and can't be transferred to anyone else, and states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty. This Limited Warranty will be enforced to the maximum extent permitted by law.

13.3 Transmitter Warranty Information

Dexcom G5 Mobile Transmitter Limited Warranty

What's Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser that the Dexcom G5 Mobile Transmitter is free from defects in material and workmanship under normal use for the period commencing on the date of first use by the original purchaser (the "Date of First Use") and expiring three (3) months thereafter; provided, that, the Date of First use occurs within five (5) months of the date of shipment (or disbursement) of the transmitter to the original purchaser.

NOTE: If you received this Transmitter as a replacement for an in-warranty Transmitter, the Limited Warranty for the original Transmitter shall continue for the Warranty Period on the original Transmitter, but the replacement is not subject to any other warranty.

What's Not Covered?

This Limited Warranty is based on the Purchaser properly using the CGM system in a timely manner and in accordance with the documentation provided by Dexcom. You are not permitted to use the CGM system otherwise. You understand that misusing the CGM system, improperly accessing it or the information it processes and transmits, "jailbreaking" your CGM system or cell phone, and taking other unauthorized actions may put you at risk, cause the CGM system to malfunction, is not permitted and voids your Limited Warranty.

This Limited Warranty does not cover:

1. Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
2. Equipment with the ID number removed or made illegible.
3. All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
4. Malfunctions resulting from the use of the Transmitter in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
5. Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
6. Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
7. Equipment which has been taken apart physically or which has had any of its software accessed in any unauthorized manner.
8. Water damage to Transmitter.
    a. Beyond specifications listed in Dexcom G5 Mobile CGM System's User Guide.
    b. User Guide is included in the Dexcom G5 Mobile System's Receiver package.
    c. Located on dexcom.com.

13.4 Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to purchaser, any defective Dexcom G5 Mobile Transmitter.

To return, you must send the Transmitter to an authorized Dexcom Technical Support Department. Make sure you package the Transmitter adequately for shipping.

The return package needs to include:

1. Transmitter
2. Sales receipt or comparable substitute proof of sale showing the date of purchase
3. Transmitter's Serial Number
4. Seller's name and address

Call Dexcom Technical Support Department for delivery information or help:

- Toll free: **1.877.339.2664**
- Charges may apply: **1.858.200.0200**

Upon receipt, Dexcom will promptly replace the defective Transmitter.

If Dexcom determines the Transmitter isn't covered by this Limited Warranty, Purchaser must pay all shipping charges for the Transmitter's return by Dexcom.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the Transmitter, and in lieu of all other warranties, expressed or implied, either in fact or by operations of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, including without limitation any warranty merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G5 Mobile CGM System or any feature or service provided by Dexcom for use with the Dexcom G5 Mobile CGM System.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and can't be transferred to anyone else, and states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty.

This Limited Warranty will be enforced to the maximum extent permitted by law.

Chapter 14

Everything Else G5:
How to Take Care of Your Dexcom G5 Mobile CGM System

14.1 Introduction

There are not a lot of moving parts in the Dexcom G5 Mobile CGM System, so maintenance is relatively simple: keep it clean, keep display device (s) dry and protected, use accessory parts, like the USB cable, etc., given to you with the system and store according to each piece's labeling instructions.

This chapter only covers Dexcom parts (sensor, transmitter, and receiver). Follow the manufacturer's instructions when caring for your smart device.

After this chapter, you will be able to:

1. Demonstrate proper maintenance
    a. Sensor
    b. Transmitter
    c. Receiver
    d. Charge receiver battery
2. Determine what accessories you may use
3. Identify the best storage methods
    a. Sensor
    b. Transmitter
    c. Receiver
4. How to safely dispose of
    a. Sensor
    b. Transmitter
    c. Receiver

14.2 Basic Maintenance

Sensor

1. Keep in sterile package until ready for use.
2. Check package label for expiration date.
    a. Expiration date format is YYYY-MM-DD (year-month-day) format.
    b. Don't use if sensor has expired.
        i. May provide inaccurate sensor glucose readings.
        ii. May be unsterile.

Transmitter

1. Keep in box until ready for use.
    a. Check transmitter and don't use if damaged.
2. Transmitter is reusable, however only by the same person.
    a. Never share transmitter with anyone.
3. Between uses, clean outside of the transmitter with damp cloth or alcohol wipes. Let dry before use or storage.
4. When not in use.
    a. Protect transmitter by returning to its packaging or another safe place.
    b. Store between 32° F-113° F.

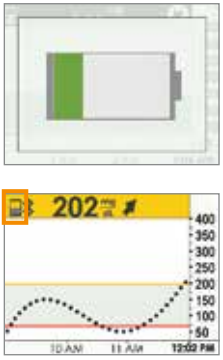
Receiver

1. Check receiver casing, if it's cracked or damaged, don't use.
    a. May get an electric shock.
2. Keep receiver dry—it is only splash resistant.
    a. Don't submerge in liquid.
    b. Don't spill fluids on receiver.
3. Keep battery charged.
    a. Only use Dexcom USB charging/download cable.
4. Keep the micro USB port cover closed if not using USB cable.
    a. Prevents fluid from getting inside receiver.

Charging Receiver's Battery

The receiver's status bar lets you see its battery level and prompts you when the battery is getting low. While the receiver is being charged, you will continue to get your sensor glucose readings if the transmitter and receiver are within 20 feet of each other.

Each charge lasts approximately three days. If your receiver's battery was drained, after charging, you may need to reset its time and date. If this is required, the system tells you to reset and takes you to the time/date setting screens.

Step	What you see	What it means	What you do
1		Low Battery	Charge your battery.
2		Micro USB Port	**Open** *USB port door.* **Plug** *USB cable* into port for recharging.

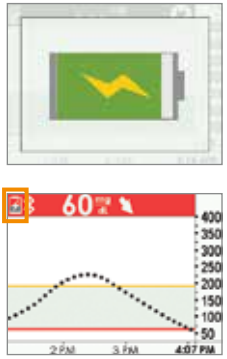
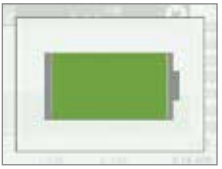
(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
3		Micro USB Cable	**Plug** into *receiver* to charge battery. Don't plug into a computer port to charge Don't use an external USB hub, it doesn't provide enough power to charge battery. Battery can only be charged using the adapter/wall charger. Charge battery before each new sensor session.
4		Wall Charger	**Plug** *USB cable* into *adapter/wall charger.* Plug wall charger into an electrical outlet to charge receiver's battery. Don't block access to the charger.

(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
5		Battery Charging	Keep charging until icons are solid.
6		Battery Charged	**Unplug** *wall charger* from outlet when fully charged.
6		USB Port Door	**Remove** *USB cable* from receiver. **Close** *USB port door* after removing USB cable to keep receiver clean and dry.

Accessories

1. Only use Dexcom-supplied parts (including cables and chargers).
    a. Use of non-Dexcom supplied parts may affect safety and performance.
2. Insert cables only as directed.
    a. Do not force cables in place.
3. Look at cables for signs of wear and tear. Do not use if worn or damaged.

There is no repair service available for any Dexcom G5 Mobile CGM System parts.

If you experience problems, call Dexcom Technical Support, available 24 hours, 7 days a week, toll free at **1.877.339.2664** or toll at **1.858.200.0200** to report the issue.

14.3 Storage

Storing your Dexcom G5 Mobile CGM System correctly helps prevents system failures.

Sensor

1. Keep the sensor in its sterile packaging until you are ready to use it.
2. Store at temperatures between 36° F-77° F.
    a. Stored outside of this range may cause inaccurate sensor glucose readings.
    b. May store in refrigerator if it's within this temperature range.
    c. Sensors should not be stored in freezer.
3. Store at humidity levels between 15%-85% relative humidity.

Transmitter

1. Keep transmitter protected when not in use.
2. Store at temperatures between 32° F-113° F.
3. Store at humidity levels between 10%-95% relative humidity.

Receiver

1. Keep receiver protected when not in use.
2. Fully charge the battery before storing for over 3 months.
3. Store at temperatures between 32° F-104° F.
4. Store at humidity levels between 10%-95% relative humidity.

14.4 Checking App and Receiver Information

CHECKING YOUR APP & RECEIVER SOFTWARE VERSION

You can check your app or receiver for information about your CGM system at any time.

Receiver

1. From the Settings menu, **press** *Up* or *Down arrows* to scroll to "Device Info."
2. **Press** *Select*. Information about your sensor session and system will show.

App

1. From Main Menu, **tap** *Settings.*
2. **Tap** *Device Info.*

Available Information

- Insertion Time
- Last Calibration
- Transmitter Battery
- Transmitter SN
- Serial Number
- Part Number
- Part Revision
- Software Number

14.5 System Disposal

Different municipalities have different requirements when throwing away electronics (receiver and transmitter) and parts that have come in contact with blood or other bodily fluids (sensor).

Consult your area's local waste management authorities for proper disposal instructions.

Taking care of your Dexcom G5 Mobile CGM System is pretty easy. In the next chapter, traveling with your Dexcom G5 Mobile CGM System, you'll learn how simple it is to see the world with your Dexcom G5 Mobile CGM System!

Chapter 15

Everything Else G5:
On the Go With Dexcom G5 Mobile CGM System: Getting Through Security

15.1 Introduction

Dexcom G5 Mobile can be a great travel companion; you can go through metal detectors, be handwanded, and even keep your receiver on during your flight.

This chapter only covers the Dexcom G5 Mobile CGM System. It doesn't cover steps you need to take when traveling with your smart device. See your smart device's instruction for use to learn how to travel with it.

After this chapter, you will be able to:

1. Explain proper procedure if you prefer a full body pat down.
2. Describe steps needed for a TSA officer to inspect Dexcom G5 Mobile CGM System components.
3. Identify when your display device(s) can be on during a flight.
4. Contact TSA directly with your security questions.

15.2 Going Through Security

Walk-Through Metal Detectors

Transmitter and Sensor

No worries about wearing your transmitter and sensor when going through security.

Go through walk-in metal detectors or, if you prefer, be handwanded without worrying about damaging your transmitter or sensor.

If you're concerned or uncomfortable about walking through the metal detector, the Transportation Security Administration (TSA) requests you tell the Security Officer you're wearing a continuous glucose monitor and want a full-body pat-down with a visual inspection of your sensor and transmitter.

Let the Security Officer know the sensor can't be removed because it's inserted under the skin.

X-Ray Machines

Receiver, Extra Sensors
Don't put your Dexcom G5 Mobile CGM System components through x-ray machines.

Before your screening process begins, ask the TSA Officer to perform a visual inspection of the receiver and your extra sensors. Place all Dexcom G5 Mobile components in a separate bag before handing over to the Security Officer.

For other medical supplies, such as medications, meters, and strips, check manufacturer's instructions or the TSA website.

Body Scanners

Use of AIT body scanners has not been studied and therefore we recommend hand-wanding or full body pat down and visual inspection in those situations.

In the Plane

You may keep the receiver on:

1. Before take-off
2. While in flight
3. After landing

The Dexcom G5 Mobile CGM System is safe for use on U.S. commercial airlines.

If you choose to use your smart device, the airlines request you put your smart devices in airplane mode. You can do this, but still keep your *Bluetooth* on and you will be able to receive sensor glucose information on your smart device.

Technical Information

The Dexcom G5 Mobile Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06.

Any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator.

This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Still Have Questions?

Visit the TSA's website if you have any questions or concerns at tsa.gov.

Email: TSA-ContactCenter@dhs.gov

Phone: Call 1.866.289.9673

Page intentionally left blank

Chapter 16

Everything Else G5:
Need Help? You're Not Alone!

Dexcom has two support teams to help you, each with their own specialty:

- Technical Support Team
- Patient Care Team

16.1 Dexcom Technical Support

Provides replacement units, resolves technical issues or takes product complaints.

Call your Dexcom Technical Support Team, 24 hours a day, 7 days a week, if something is wrong with your Dexcom G5 Mobile CGM System.

By Phone

Dexcom Technical Support Phone Numbers:

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Email: TechSupport@dexcom.com

If you prefer to email, to help us help you best, include the following information in your email:

- Name of patient
- Date of Birth
- The technical issue you
- When the problem happened (date and time)
- Patient's address
- Patient's phone number
- Item SKU number and description (e.g., name of the device)
- Lot number and/or serial number(s) of affected devices (e.g., sensor)

What Can They Help Me With?

The Dexcom Technical Support Team helps you with all CGM system related issues as well as software related issues.

Dexcom Technical Support does not offer medical advice.

16.2 Patient Care Team

The Patient Care Team (PCT) is a group of Certified Diabetes Educators (CDE®) and Registered Nurses (RNs) offering you customer care and individualized education services around Dexcom CGM.

Your PCT provides education and support throughout your CGM experience, such as:

- Initial CGM Product Training
- Ongoing Dexcom product education (e.g., how to use a specific feature)
- How to maximize Dexcom CGM use
- Dexcom CGM reporting software and features
- How to review and understand Dexcom CGM reports

By Phone

Available Monday-Friday 5:30 am-8:00 pm PST (subject to change)

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Email: patientcare@dexcom.com

If you prefer to email, to help us help you best, include the following information in your email:

- Name
- DOB
- Contact phone number
- Reason for inquiry or education needed

For additional Dexcom CGM education, check the Dexcom website:
dexcom.com/web-based-education

16.3 Sales Support Team

Inside Sales Support Team

For help with:

- First-time orders
- Re-orders
- Tracking shipments
- Locating a local Dexcom representative

By Phone

Dexcom Inside Sales Support Phone Numbers:

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Dexcom Inside Sales Support Email: CustomerService@dexcom.com

By Fax

1.877.633.9266

16.4 Corporate

Dexcom Website:
Dexcom.com

Dexcom Address:
6340 Sequence Drive
San Diego, CA 92121

Page intentionally left blank

Chapter 17

Everything Else G5:
Technical Information

17.1 Device Performance Characteristics

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the Dexcom G5 Mobile CGM System performs.

The Dexcom G5 Mobile CGM System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is "calibrated" using a commercially available blood glucose meter. Once calibrated, the System reports glucose readings up to every 5 minutes. The System was evaluated clinical studies in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, subjects performed self-monitoring blood glucose meter tests at home to assess the System performance in real use environment.

Although the performance characteristics of the System are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G5 Mobile CGM System.

Clinical Study Overview

The System performance was evaluated in four separate prospective clinical studies. Two studies included adults, and two studies included pediatrics. In the following sections and tables, the studies will be identified as follows:

Adult Studies (18 years and older)
Original Adult Study: the Receiver included software version SW10050
Software 505 Adult Study: the Receiver included software version SW10505

Pediatric Studies (2 to 17 years)
Original Pediatric Study: the Receiver included software version SW10050
Software 505 Pediatric Study: the Receiver included software version SW10505

The Dexcom G5 Mobile CGM System incorporates the algorithm from software version SW10505 and has a new software number.

Overview of Adult Studies

The System performance for adults was evaluated in two separate prospective clinical studies: **Original Adult** Study (software SW10050) and the **Software 505 Adult** Study (software SW10505).

Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, and the number of clinic days each subject participated in during the study. An overview of each study is provided here.

The **Original Adult** Study enrolled 72 subjects, and the **Software 505 Adult** Study enrolled 51 subjects. All subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original Adult** Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505 Adult** Study, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

Subjects in both studies used the System for seven days. In the **Original Adult** Study, thirty-six subjects each wore 2 sensors; in the **Software 505 Adult** Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original Adult** Study, subjects used the LifeScan® OneTouch® Ultra®2 meter and in the **Software 505 Adult** Study, subjects used Bayer's CONTOUR® NEXT USB meter.

In the **Original Adult** Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505 Adult** Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original Adult** Study. While using the System in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the System were reported every 5 minutes and paired with YSI values in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the "SMBG."

Overview of Pediatric Studies

The System performance for children and adolescents was evaluated in two separate prospective clinical studies: the **Original Pediatric** Study (SW10050) and the **Software 505 Pediatric** Study (SW10505). Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, the length of time subjects were evaluated in a controlled clinic environment and whether or not subjects ages 13-17 had their glucose levels intentionally manipulated during the study. An overview of each study is provided here.

The **Original Pediatric** Study enrolled 176 subjects, with 16% of subjects younger than 6-years old, and the **Software 505 Pediatric** Study enrolled 79 subjects, with 20% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. In the **Original Pediatric** Study, about 99% of subjects had Type 1 diabetes and 1% had Type 2 diabetes. In the **Software 505 Pediatric** Study, all subjects had Type 1 diabetes. Sensors were inserted in either the abdomen or upper buttocks.

Subjects in all studies used the System for seven days. In the **Original Pediatric** Study, all subjects wore 2 sensors; in the **Software 505 Pediatric** Study, all subjects wore 1 sensor only. Throughout

the 7-day wear period, the sensors were calibrated with an average of 2 fingersticks per day (approximately once every 12 hours), using self-monitoring blood glucose (SMBG) meter values. The **Original Pediatric** Study used the LifeScan® OneTouch® Verio® IQ meter; the **Software 505 Pediatric** Study used Bayer's CONTOUR® NEXT USB meter.

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the System in the clinic, subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." In the **Original Pediatric** Study, subjects' glucose levels were not intentionally manipulated during this study; in the **Software 505 Pediatric** Study, subjects ages 13-17 had their glucose levels intentionally manipulated during the clinic session. Readings from the System were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the "SMBG."

Table 1-A. System Agreement to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

[1] *CGM readings are within 40-400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 1-B. System Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40-60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61-80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81-180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181-300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301-350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351-400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

[1] *CGM readings are within 40-400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Agreement Relative to YSI

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL

or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% are provided in Table 1-A and 1-B. The tables are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study).

For example, in the **SW10505 Adult** Study (Table 1-A), the total number of data pairs considered in the analysis was 2263. Of these, 93% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within ± 20% of YSI blood glucose values > 80 mg/dL.

Table 2-A. Number and Percentage of YSI Values When CGM Readings are "LOW" or "HIGH" (Adult)

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
"HIGH"	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

[1] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 2-B. Number and Percentage of YSI Values When CGM Readings are "LOW" or "HIGH" (Pediatric)

CGM Readings	Study[1]	CGM-YSI Pairs	YSI mg/dL					Total
			< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	

CGM Readings	Study[1]	CGM-YSI Pairs	YSI mg/dL					Total
			> 340	> 320	> 280	> 240	≤ 240	
"HIGH"	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Agreement When CGM Reads "LOW" or "HIGH"

The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Receiver Status Box. When the Dexcom G5 Mobile System determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Table 2-A and 2-B. The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for "LOW"), and when YSI values were greater than certain glucose levels (for "HIGH").

For example, in the **Software 505 Adult** Study (Table 2-A), when the System displayed “LOW” (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70 mg/dL. When the System displayed “HIGH” (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Adult Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Number of Paired CGM-YSI
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201- 250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251- 300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301- 350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351- 400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Adult Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Number of Paired CGM-YSI
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40-60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61-80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81-120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121-160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161-200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201- 250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251- 300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301- 350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351- 400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Table 3-C. Concurrence of CGM Readings and YSI Values (Original Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Number of Paired CGM-YSI
< 40	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40-60	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61-80	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81-120	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121-160	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161-200	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201- 250	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251- 300	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301- 350	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351- 400	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-D. Concurrence of CGM Readings and YSI Values (Software 505 Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	Number of Paired CGM-YSI
< 40	6%	25%	63%	6%	0%	0%	0%	0%	0%	0%	0%	16
40-60	0%	33%	60%	6%	1%	0%	0%	0%	0%	0%	0%	86
61-80	0%	8%	64%	26%	2%	0%	0%	0%	0%	0%	0%	142
81-120	0%	1%	15%	69%	13%	1%	1%	0%	0%	0%	0%	314
121-160	0%	0%	0%	15%	66%	18%	1%	0%	0%	0%	0%	313
161-200	0%	0%	0%	1%	18%	66%	15%	0%	0%	0%	0%	355
201- 250	0%	0%	0%	0%	1%	17%	68%	14%	0%	0%	0%	444
251- 300	0%	0%	0%	0%	0%	0%	26%	58%	16%	0%	0%	336
301- 350	0%	0%	0%	0%	0%	0%	4%	40%	46%	9%	0%	209
351- 400	0%	0%	0%	0%	0%	0%	3%	14%	62%	21%	0%	63
> 400	0%	0%	0%	0%	0%	0%	4%	13%	29%	38%	17%	24

Concurrence of System and Laboratory Reference

Table 3-A (**Original Adult** Study), 3-B (**Software 505 Adult** Study), 3-C (**Original Pediatric** Study) and 3-D (**Software 505 Pediatric** Study) are categorized by ranges of CGM glucose readings. These tables describe, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings. For example, based on the **Software 505 Adult** Study, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 72% of time.

Table 4-A. System Difference to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40-60	Original	512	-10.0	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61-80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81-180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181-300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301-350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351-400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

**For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).*

Table 4-B. System Difference to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	2922	13.5%	11.6%	17.4%	13.5%
	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40-60	Original	19	-18.1	-9.1	19.2	9.1
	Software 505	86	-15.3	-13.2	16.1	13.2
*61-80	Original	76	-3.7	-2.3	13.4	10.6
	Software 505	142	-4.8	-1.0	11.8	7.7
81-180	Original	1155	11.9%	9.7%	17.0%	13.0%
	Software 505	805	1.9%	0.7%	10.6%	8.1%
181-300	Original	1380	14.8%	12.4%	17.4%	13.3%
	Software 505	957	2.2%	1.0%	8.1%	6.5%
301-350	Original	206	19.2%	15.9%	19.4%	15.9%
	Software 505	209	7.8%	6.5%	11.0%	7.9%
351-400	Original	86	18.5%	15.5%	19.1%	15.5%
	Software 505	63	14.9%	11.6%	15.2%	11.6%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

**For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).*

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL and the System reading is 90 mg/dL, a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected.

In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or "distance" between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between System readings and YSI values.

Accuracy measures in differences for both the **Original Adult** and **Software 505 Adult** Studies are summarized in Table 4-A. Accuracy measures in differences for both the **Original Pediatric** and **Software 505 Pediatric** Studies are summarized in Table 4-B. Table 4-A and 4-B are categorized within CGM glucose ranges.

For example, in the **Software 505 Adult** Study (Table 4-A), overall, on average, the System reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.0% or less than the YSI blood glucose values.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	Software 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	Software 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	Software 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	Software 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	Software 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	Software 505	91%	9%	93%	7%

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 5-C. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	Software 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	Software 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	Software 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	Software 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	Software 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	Software 505	82%	18%	100%	0%

[1] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Table 5-A, 5-B and 5-C. Table 5-A represents the hypoglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 5-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes.

Table 5-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? In the **Software 505 Adult** Study (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and above 70 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? In the **Software 505 Adult** Study (Table 5-A), when your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	Software 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	Software 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	Software 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	Software 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	Software 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	Software 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	Software 505	69%	31%	84%	16%

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 6-C. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

[1]*Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 6-A, 6-B and 6-C. Table 6-A represents the hyperglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 6-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30

minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? In the **Software 505 Adult** Study (Table 6-A), when your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? In the **Software 505 Adult** Study (Table 6-A), when your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

Table 7-A. Percentage of System Readings[1] within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Adult)

Time from Calibration	Study[2]	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 7-B. Percentage of System Readings[1] within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Pediatric)

Time from Calibration	Study[2]	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, Systems were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Table 7-A and 7-B.

Table 8-A. Sensor Stability Relative to YSI (Accuracy Over Time[1]) - (Adult)

Day of Wear	Study[2]	Number of Paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 8-B. Sensor Stability Relative to YSI (Accuracy Over Time[1]) - (Pediatric, Ages 6-17 Years)

Day of Wear	Study[2]	Number of Paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	1016	21.2%	15.8%	48%	61%	78%	15%
	Software 505	740	12.7%	8.5%	75%	83%	91%	4%
Day 4	Original	810	16.0%	13.9%	52%	66%	87%	3%
	Software 505	795	8.1%	6.7%	89%	97%	100%	0%
Day 7	Original	1096	15.1%	11.3%	63%	76%	89%	4%
	Software 505	727	10.4%	8.4%	80%	91%	98%	1%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 8-C. Sensor Stability Relative to SMBG (Accuracy Over Time[1]) - (Pediatric, Ages 2-17 Years)

Day of Wear	Study[2]	Number of Paired CGM-SMBG	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Day 1	Original	3216	18.8%	14.2%	53%	65%	81%	10%
	Software 505	893	14.8%	10.7%	64%	79%	91%	5%
Day 2	Original	2148	16.2%	12.4%	60%	74%	87%	6%
	Software 505	436	13.2%	10.4%	69%	81%	95%	3%
Day 3	Original	1977	15.2%	11.0%	63%	76%	89%	5%
	Software 505	441	13.8%	11.3%	66%	77%	91%	2%
Day 4	Original	2830	14.0%	10.9%	66%	79%	91%	4%
	Software 505	850	10.7%	8.5%	79%	91%	97%	1%
Day 5	Original	1768	15.4%	10.7%	67%	78%	90%	5%
	Software 505	374	11.4%	8.7%	74%	86%	96%	1%
Day 6	Original	1704	14.3%	9.8%	68%	79%	90%	4%
	Software 505	410	12.3%	9.2%	72%	80%	93%	2%
Day 7	Original	2675	12.4%	9.2%	72%	83%	94%	3%
	Software 505	860	11.3%	8.6%	79%	90%	96%	2%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Sensor Stability

Relative to YSI

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% , 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8-A and 8-B showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Relative to SMBG (Pediatric Study)

Performance was also estimated by calculating the percentage of system readings within various percentages of the SMBG values at each day of the sensor wear period (Table 8-C). The average and median of the absolute percent differences are included in the table.

Precision of System Readings

A subset of subjects wore two Systems at the same time. This was to look at how similarly two Systems function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time.

In the **Original Adult** Study, 36 subjects wore two Systems. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. In the **Original Pediatric** Study, all subjects wore two Systems. Results showed that System readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Software 505 Adult** and **Software 505 Pediatric** Studies so precision data was not collected.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

In the **Original Adult** Study, 108 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

In the **Software 505 Adult** Study, 51 sensors were evaluated. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

In the **Original Pediatric** Study, 351 sensors were evaluated. Eighty-five percent (85%) of the sensors lasted until Day 7 (145-168 hours).

In the **Software 505 Pediatric** Study, 77 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours).

Table 9-A. Number of Readings Provided by Each Sensor Over 7-Days (Adult)

% of Total Possible Readings Provided	Study[1]	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0-25%	Original	167-491	2%
	Software 505	0	0%
26-50%	Original	719-914	4%
	Software 505	856-856	2%
51-75%	Original	1267-1267	1%
	Software 505	1253-1253	2%
76-100%	Original	1811-1992	94%
	Software 505	1497-1992	96%

[1] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 9-B. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric)

% of Total Possible Readings Provided	Study[1]	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0-25%	Original	103-427	3%
	Software 505	60-223	4%
26-50%	Original	569-954	3%
	Software 505	877-891	3%
51-75%	Original	1006-1484	9%
	Software 505	1131-1342	3%
76-100%	Original	1518-1992	86%
	Software 505	1623-1990	91%

[1] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 10-A. System Readings Within Wear Days (Adult)

Statistic	Study[1]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days[2]
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
Standard Deviation	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

[1] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

[2] *A total of 108 sensors were included with the **Original** Study and 51 sensors were included with the **Software 505** Study.*

Table 10-B. System Readings Within Wear Days (Pediatric)

Statistic	Study[1]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days[2]
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
Standard Deviation	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

[1] *Both sets of study data are presented and are labeled as* ***Original*** *(SW10050) or* ***Software 505*** *(SW10505).*

[2] *A total of 108 sensors were included with the* ***Original*** *Study and 77 sensors were included with the* ***Software 505*** *Study.*

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are "skipped." Table 9-A and 9-B estimate the number of readings you can expect to receive from the System over the entire 7-day period after calibration. Table 10-A and 10-B show the number of readings you can expect to receive from the System within each system wear day.

For the **Software 505 Adult** Study (SW10505), 96% of Systems provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings) as seen in Table 9-A. Adjusted within each system wear-day, the System in the **Software 505 Adult** Study provided an average of 98% of all expected glucose readings (288) as seen in Table 10-A.

Table 11-A. System Agreement to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40-60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61-80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81-180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181-300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301-350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351-400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 11-B. System Agreement to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	16318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40-60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61-80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81-180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181-300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301-350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351-400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

Table 12-A. System Difference to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40-60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61-80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81-180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181-300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301-350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	-0.0%	0.0%	8.3%	6.0%
351-400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	86	3.9%	3.2%	8.1%	6.7%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

**For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).*

Table 12-B. System Difference to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	16318	2.2%	0.9%	15.3%	11.1%
	Software 505	4264	-0.7%	-1.1%	12.5%	9.5%
*40-60	Original	487	-22.1	-17.0	23.9	18.0
	Software 505	240	-15.9	-14.0	16.9	14.0
*61-80	Original	1340	-11.8	-8.0	17.0	11.0
	Software 505	399	-7.8	-6.0	13.7	10.0
81-180	Original	7084	1.1%	-1.0%	15.4%	11.4%
	Software 505	1650	-1.2%	-2.6%	12.1%	9.5%
181-300	Original	5627	5.7%	3.4%	13.5%	9.5%
	Software 505	1526	1.7%	0.9%	10.1%	7.7%
301-350	Original	1176	9.6%	7.2%	14.2%	10.4%
	Software 505	319	6.7%	5.9%	11.8%	8.9%
351-400	Original	604	12.7%	10.2%	16.1%	11.9%
	Software 505	130	12.0%	8.9%	15.7%	10.6%

[1] *CGM readings are within 40 to 400 mg/dL, inclusive.*

[2] *Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).*

**For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).*

Agreement and Accuracy Relative to SMBG

Agreement between the System and blood glucose values is also characterized using paired System and SMBG results (Table 11 to 12). The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the System in their daily diabetes management when comparing the System readings to their home blood glucose meter results. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL, the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within

15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated.

For example, if the System reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the System readings to be within 20% of the SMBG values 85% of the time for the **Software 505 Adult** Study, as seen in Table 11-A.

Overall, the System in the **Software 505 Adult** Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads lower in 2.7% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 8.6% or less different than SMBG values, as seen in Table 12-A.

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the studies. Mild to moderate skin irritation, such as erythema or edema, occurred at the sensor needle insertion area or around the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

17.2 Product Specifications

User is the single use operator in the home environment.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Do not touch the metal connectors on the bottom of the transmitter and other open connectors on the receiver, charging cable and charger.

Sensor Product Specifications

Glucose Range	40-400 mg/dL
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	40-400 mg/dL
Storage Condition	Temperature: 36° F-77° F Humidity: 15%-85% RH
Sterilization	Sterile by radiation

Transmitter Product Specifications

Part Number	9438-06
Dimensions (Including Sensor Pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches
Weight (Including Sensor Pod)	0.4 ounces
Power Supply	Silver oxide batteries (not replaceable)
Operational Conditions	Ambient temperature is 10° C-42° C (50° F-107.6° F) Equilibrium temperature of less than 0.5° C (0.9° F) above ambient Humidity: 10%-95% RH
Storage Conditions	Temperature: 32° F-113° F Humidity: 10%-95% RH
Operating Altitude	-1300 feet to 13800 feet
Limited Warranty	3 months
Moisture Protection	IP28: Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours
Protection Against Electrical Shock	Type BF applied part

Transmitter Performance Characteristics

Parameter	Performance Characteristic
TX/RX Frequencies	2.402-2.480 GHz
Bandwidth	1.02 MHz
Maximum Output Power	1.0 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps
Data Communication Range	20 feet

The Dexcom G5 Mobile CGM System is safe for use on U.S. commercial airlines. The Dexcom G5 Mobile CGM System is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06, any M-PED that meets this standard in all

modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter (P/N 9438-06) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Receiver Product Specifications

Part Number	MT22719
Reading Frequency	Every 5 minutes
Dimensions	Length: 4.0 inches Width: 1.8 inches Thickness: 0.5 inches
TX/RX Frequencies	2.402-2.480 GHz
Bandwidth	1.22 MHz
Maximum Output Power	2.5 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps

(Continued on next page)

(Continued from previous page)

Weight	2.4 ounces
Receiver Input	5V DC, 1A
Power Supply	MT21255
Communication Range	20 feet
Memory Storage	30 days of glucose data 7 days of tech support data
Re-Chargeable Battery Use	3 days
Charging Time	3 hours wall outlet The device behaves normally while being charged Do not hold the receiver while charging for over a minute There are no risks to connecting any part of the system to an MSO (Multiple Socket Outlet)
Storage/Operating Conditions	Temperature: 32° F-104° F Humidity: 15%-95% RH, (Storage 10%-95% RH)
Operating Altitude	-1300 feet to 13800 feet
Medium Priority Alarm Audible Output	50 dBa at 1 meter
Moisture Protection	IP22: Vertically falling drops Protection against insertion of large objects and dripping water
Limited Warranty	1 year
Control Classification	Class II equipment

No cleaning methods are recommended or tested for the receiver. The warranty life of the receiver is 1 year. The service life for the accessories is noted to be up to one year. If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location. Do not connect the receiver to any equipment not specified in IFU.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver (MT22719) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

Receiver Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11** **IEC 60601-1-11**	0% U_T for 1 cycle 0% U_T for 0.5 cycle at 8 phase angles 70% U_T (30% dip in Ut) for 25 cycles 0% U_T for 250 cycles	0% U_T for 1 cycle 0% U_T for 0.5 cycle at 8 phase angles 70% U_T (30% dip in Ut) for 25 cycles 0% U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field **IEC 61000-4-8**	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G5 Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G5 Mobile System should ensure that it is used in such an environment.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Conducted RF **IEC 61000-4-6** **(Receiver only)**	3 Vrms 150 kHz to 80 MHz	6 Vrms	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Recommended Separation Distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:
Radiated RF **IEC 61000-4-3**	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	

NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G5 MOBILE System is used exceeds the applicable RF compliance level above, the Dexcom G5 MOBILE System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G5 MOBILE System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Dexcom G5 Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G5 Mobile System should ensure that it is used in such an environment.

Electromagnetic Emissions Specifications

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Dexcom G5 Mobile System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Dexcom G5 Mobile System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended in the next table, according to the maximum output power of the communications equipment. Portable and mobile RF equipment include: baby monitors, *Bluetooth* wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Minimum Recommended Distance Between Other RF Transmitters and the Dexcom Transmitter/Receiver

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ P^{½}$	**80 MHz to 800 MHz** $d = 1.2\ P^{½}$	**800 MHz to 2.5 GHz** $d = 2.3\ P^{½}$
0.01	0.12	0.12	0.23

(Continued on next page)

(Continued from previous page)

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 P^{½}$	80 MHz to 800 MHz $d = 1.2 P^{½}$	800 MHz to 2.5 GHz $d = 2.3 P^{½}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

USB Charging/Download Cable* Specifications

Part Number	MT20655
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	3 feet

**The power supply/charger can be connected to the USB charging/download cable for charging using an AC power outlet. Misuse of the USB cable can present a strangulation risk. Isolation of system is by unplugging charger from wall.*

Power Supply/Charger Specifications

Part Number	MT21255
Class	II
Input	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC Output	5V DC, 1A (5.0 Watts)

17.3 FCC Requirements

The transmitter and receiver covered by this user guide have been certified under FCC ID:

- G5 Mobile Transmitter: PH29715
- G5 Mobile Receiver: PH29496

Although the transmitter and receiver have been approved by the Federal Communications Commission, there is no guarantee that they will not receive interference or that any particular transmission from either device will be free from interference.

Compliance Statement (Part 15.19)
This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. No modification of the equipment is allowed as it could create an unsafe condition.

FCC Interference Statement (Part 15.105 (b))
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

Page intentionally left blank

Chapter 18

Everything Else G5: Troubleshooting

18.1 Introduction

Sensor pod not sticking? Prompt won't go away? Not getting your sensor glucose readings? Don't know when to replace your transmitter? This chapter will help you figure it out!

Troubleshooting sections are categorized by function or system component. The solutions here are meant to be brief and not all inclusive, some have audible prompts, and others don't. When more detailed answers or preventative measures are in a chapter, you'll get a brief explanation here, and then get directed to the applicable chapter and section.

After looking at the troubleshooting chapter, are you still not sure what to do? Or maybe your problem is hardware (e.g., receiver or transmitter failure).

If your problem is not found here, follow the steps listed on your app screen, or call Technical Support.

Please call the Dexcom Technical Support Team, 24/7, toll free at **1.877.339.2664** or toll at **1.858.200.0200** if any of these errors continue and the instructions don't resolve the issue.

18.2 Safety Statements

Following are the Safety Statements for the Troubleshooting chapter.

WARNING

Do: *Calibrate at least once every 12 hours.*

Why: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings.

Consequences: Missing severe low (hypoglycemia) or high (hyperglycemia) Alarm or Alerts.

PRECAUTION

Do: *Enter the exact BG value displayed on your BG meter within five minutes of a carefully performed fingerstick measurement.*

Why: Entering the wrong blood glucose values, or waiting more than five minutes before entry, might affect sensor accuracy.

Consequences: You may miss a severe low or high glucose events.

PRECAUTION

Don't: *Never prevent communication between transmitter and display devices.*
Do: *Keep smart device and receiver within 20 feet of transmitter and away from obstructions.*

Why: If your transmitter display device(s) are more than 20 feet apart or are separated by an obstruction, they might not communicate.

Types of obstruction differ and not all types have been tested. Obstructions can include water, walls, metal, etc.

Water (e.g., swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high Alarm or Alerts.

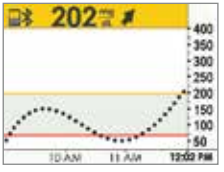
18.3 Troubleshooting

No Alarm/Alerts

Device	What you see	Problem	What you do
Smart Device: In App		Not receiving Alerts	See Chapter 11. **Check** *Alarm/Alerts*, sound and/or vibrations for notifications are on. **Check** your smart device is not on mute (if applicable).
Receiver			

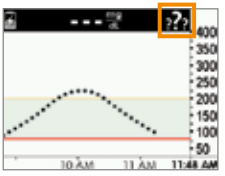
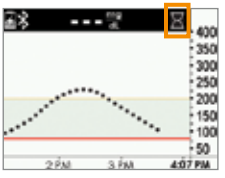
(Continued on next page)

Sensor Glucose Readings

Device	What you see	Problem	What you do
BG Meter		Sensor readings and BG meter glucose values often don't show the same	See Chapter 7. Differences are not uncommon. Readings from different body fluids reflect different numbers: **Meter** - from blood **Sensor** - from interstitial fluid **20/20 Rule** If the meter shows 80 or less, CGM should read within ± 20 points. If the meter shows 80 or above, the CGM should read ± 20%. Example: a 202 mg/dL sensor reading and a 188 mg/dL glucose meter value = a 7% difference (this is still considered accurate). Outside of 20/20 rule: **Calibrate** again.
Smart Device: In App			
Receiver			

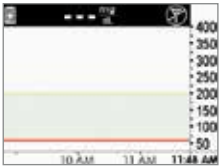
(Continued on next page)

(Continued from previous page)

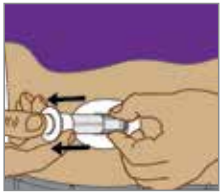
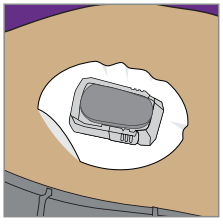
Device	What you see	Problem	What you do
Smart Device: In App		Not getting sensor glucose readings	See Chapter 9. *Don't* calibrate. **Wait** for more prompts. System may correct problem itself and continue to provide sensor glucose readings. 3 hours since last sensor reading: **call** Technical Support (see Section 16.1).
Receiver			
Smart Device: In App		Not getting sensor glucose readings	See Chapter 9. **Wait** System will often resolve itself. If this continues for an extended period of time, call Technical Support to report error (see Section 16.1).
Receiver			

(Continued on next page)

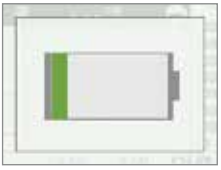
(Continued from previous page)

Device	What you see	Problem	What you do
Smart Device: In App		System display device and transmitter not communicating	See Chapter 9. *Don't* calibrate. **Wait** 10 minutes. **Move** *display device* and *transmitter* within 20 feet of each other without obstruction. **Wait** another 10 minutes. **App (if not resolved):** 1. **Go** to *Settings*. 2. **Tap** *Bluetooth*. 3. **Turn** *Bluetooth Off* and *On*.
Receiver	 		
Smart Device: In App		No sensor glucose readings	See Chapter 7. **Wait** up to 2 hours. System is counting down to when you do your initial calibration.
Receiver			

Applicator

Picture	Problem	What you do
	Safety lock stuck	See Chapter 6. **Pull** *safety lock* straight out: • Away from your body • Follow direction of safety lock *Up Arrow*
	Collar won't pull up	See Chapter 6. **Use** force when pulling the collar up. **Check** *white plunger* is completely down—flush to the applicator barrel.
	Can't remove transmitter latch	See Chapter 6. Don't pull it straight off. **Hold** *sensor pod* with one hand. **Twist** *transmitter latch* with other hand to break transmitter latch off.
	Sensor pod won't stick	See Chapter 6. **Put** medical tape over sensor pod's white adhesive patch (e.g., Blenderm). **Don't** place tape over the transmitter.

Hardware Error

Device	What you see	Problem	What you do
Receiver		Won't turn on: Battery dead	See Chapter 4. **Charge** *receiver* using electrical outlet, not computer/laptop. Full charge may take up to five hours.
Receiver		After full charge session: Won't turn on	See Chapter 4. **Reset** *receiver.* **Connect** *receiver* to *charger.* **Insert** end of paper clip into small circular hole on receiver's back. **Push down** on paper clip. Receiver will vibrate. Processing screen appears. **Charge** *receiver.*
Receiver		Receiver Low Battery	See Chapter 4. **Charge** *receiver.*

(Continued on next page)

(Continued from previous page)

Device	What you see	Problem	What you do
Receiver		Corrupted database	See Chapter 16. **Write down** error code. Contact Dexcom Technical Support (see Section 16.1). **Check** BG value using BG meter. **Prompt:** Vibrates one time for four seconds and four beeps.
Receiver		System Recovery	See Chapter 16. Do nothing. Receiver is able to continue to work and recover from an error. App: **Tap** *OK* to clear Alert. Receiver: **Press** *Select* to clear Alert.
Smart Device: In App		No *Bluetooth*	See Chapter 5. **Go** to smart device's *Settings*. **Make sure** *Bluetooth* is On. If problem persists, please contact device's manufacturer.

Calibration Error

Device	What you see	Problem	What you do
BG Meter		System will not accept calibration if outside of the 40-400 mg/dL range	See Chapter 7. **Wait** until your glucose is between 40-400 mg/dL. **Calibrate** only when your BG meter values are between 40-400 mg/dL.
Smart Device: In App		System didn't accept recent calibration (see Sensor Glucose Readings troubleshooting for a possible reason) No sensor glucose readings will be displayed until error is resolved	See Chapter 7. **Wait** 15 minutes. **Enter** 1 calibration. If error screen still appears enter 1 more BG meter value. **Wait** 15 minutes. If no sensor glucose readings appear on the display, the sensor needs to be replaced. Call Technical Support to report error (see Section 16.1). App: Follow same instructions. **Tap** *question mark* to get more information.
Receiver			

(Continued on next page)

(Continued from previous page)

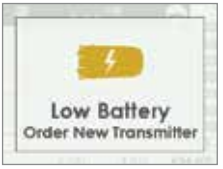
Device	What you see	Problem	What you do
Smart Device: In App		System didn't accept recent calibration	See Chapter 7. **Wait** 15 minutes. **Enter** 1 BG meter value. **Wait** 15 more minutes. If error screen still appears enter 1 more BG meter value. **Wait** 15 minutes. If no sensor glucose readings appear on the display, the sensor needs to be replaced. **Call** Technical Support (see Section 16.1) to report error.
Receiver			

Transmitter Error:

Device	What you see	Problem	What you do
Smart Device: In App		Transmitter not working Sensor session automatically stopped No sensor glucose readings displayed	See Chapter 16. **Contact** Technical Support to report issue (Section 16.1). **Start checking** BG value using BG meter. App: **Tap** *OK* to clear Alert. Receiver: **Press** *Select* to clear. Will not re-alert once cleared. **Order** new transmitter.
Receiver			
Smart Device: In App		Pairing Failed	See Chapter 6. Check Transmitter SN in display device is correct. If wrong: **Stop** *sensor session*. **Re-Enter** correct transmitter SN. App: Menu > Trans SN > **Enter** correct SN Receiver: Settings > Trans SN > **Enter** correct SN If correct: Call Tech Support (see Chapter 16).
Receiver			

(Continued on next page)

(Continued from previous page)

Device	What you see	Problem	What you do
Smart Device: In App		Transmitter Low Battery	See Chapter 16. App: **Tap** *OK* to clear Receiver: **Press** *Select* to clear. Will not re-alert once cleared. **Order** new transmitter.
Receiver			

Page intentionally left blank

Chapter 19

Everything Else G5:
Symbols on Package Labels

The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G5 Mobile System.

Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

	Use By Date	LOT	Batch/Lot Number
	Caution	REF	Part/Catalog Number
	Date of Manufacture	STERILE R	Sterile by Radiation
	Do Not Reuse		Temperature Limitation
SN	Serial Number	IP28	IP28: Protection Against Insertion of Large Objects and Immersion in Water
	Class II Equipment	IP22	IP22: Protection Against Insertion of Large Objects and Dripping Water
	Alternating Current		Direct Current

(Continued on next page)

(Continued from previous page)

	Type BF Applied Part		Authorized Representative in the European Community
	Manufacturer		Non-Ionizing Radiation
	Humidity Limitation		Marking Certifies Device Meets European Council Directive 93/42/EEC
	European Union WEEE Directive 2012/19/EU		Do Not Use if Package is Damaged
	Electrical Equipment Designed Primarily for Indoor Use	**SB**	Ship By Date
	Input	**Rx Only**	Prescription Required
	Keep Dry		MR Unsafe
	Refer to Instruction Manual/Booklet		*Bluetooth*

5

SHARING IS CARING

- Dexcom Share

Page intentionally left blank

Chapter 20

Sharing Is Caring:
Dexcom Share

20.1 Learning About Dexcom Share

Glossary

Airplane Mode	A setting on a smart device where wireless features are disabled in order to comply with airline regulations.
Application or App	A software program, such as the Dexcom G5 Mobile App and the Dexcom Follow App, designed to run on a smart device.
App Store	Internet store for downloading applications to a smart device.
Blood Glucose Meter	A device used to measure how much glucose is in the blood.
BG Value	The measurement of glucose in the blood.
Bluetooth	*Bluetooth* wireless technology allows devices to wirelessly communicate with each other.
Default	A manufacturer's preset option for a device setting.
Delay	Amount of set time that passes before a notification is sent to a Follower.
Dexcom Share Cloud	A secure online storage server where Dexcom Share feature information is stored and then shared with Followers.
Dexcom Follow App	Gets the Sharer's glucose information and prompt data from the Dexcom Share Cloud.
Dexcom G5 Mobile/G4 PLATINUM Sensor	The Dexcom G5 Mobile System part that includes an applicator and sensor wire.

(Continued on next page)

(Continued from previous page)

Dexcom G5 Mobile System	CGM system made of a sensor, transmitter, and smart device/ receiver.
Dexcom G5 Mobile Transmitter	The Dexcom G5 Mobile System part that wirelessly sends glucose information to the Dexcom G5 Mobile App.
Dexcom G5 Mobile App	Receives glucose information from the Dexcom G5 Mobile Transmitter. Sends glucose information to the Dexcom Cloud using an Internet connection.
Dexcom Share	Secondary notification using the following parts: • Dexcom G5 Mobile System • *Bluetooth* wireless technology • Sharer's smart device • Dexcom G5 Mobile App • Internet • Follower's smart device • Dexcom Follow App
Do Not Disturb	A setting on a smart device where all incoming calls, alerts, and notifications are silenced. Do Not Disturb can be set to specific times and can be set to allow exceptions (people who can disturb you).
Follower	A person that gets the Sharer's shared information in the Dexcom Follow App.
Follow Dashboard™	On the Dexcom Follow App, the Follow Dashboard shows the glucose information of up to five (5) Sharers.
Follower's Smart Device	Runs the Dexcom Follow App.
Hyperglycemia	High BG. Same as "high." The default high alert in the Dexcom G5 Mobile CGM System is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemic setting for you.

(Continued on next page)

(Continued from previous page)

Hypoglycemia	Low BG. Same as “low.” The default low alert the Dexcom G5 Mobile CGM System is set to 80 mg/dL. Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.
Invite/Follow Invitation Email	An email request for a person to download the Dexcom Follow App and get the Sharer’s shared information.
Jailbroken	The removal of limitations set by the manufacturer on a smart device. Do not use jailbroken smart devices with Dexcom Share.
mg/dL	Milligrams per deciliter. The standard unit of measure for sensor glucose information in the United States.
Mobile Data Connections	Cellular networks, such as 3G, 4G and LTE™, used by a smart device to access the Internet.
No More Data prompt	Prompts the Follower when the Sharer is unable to share glucose information.
Not Sharing	When the Sharer chooses to temporarily not share glucose data with the Follower.
Obstruction	An object that stops the wireless communication between devices, such as wall thickness or radio waves.
Profile	Located in Follow Dashboard and displays the Sharer’s glucose information, trend arrow and profile picture.
Prompt	A visual message that appears on the screen of the Follower’s smart device. Prompt may also include a sound, depending on the smart device’s settings.
Range	Maximum distance two devices can communicate wirelessly without obstruction.

(Continued on next page)

(Continued from previous page)

Real-Time CGM	Data the Sharer receives on the Dexcom G5 Mobile App. Although your Dexcom Follow App might be similar to what you see on your app, it cannot be considered real-time because there are layers of communication between the Dexcom G5 Mobile App and the Dexcom Follow App.
Repeat	Amount of time the Follower chooses before they wish to receive a repeated notification.
Sensor Glucose Reading	A glucose measurement taken by the Dexcom G5 Mobile System.
Sharer	The person who uses the Dexcom G5 Mobile System.
Sharing	The act of electronically transmitting glucose information from the Sharer's smart device to the Follower's smart device.
Simultaneous Voice and Data	The ability to make a phone call and access the Internet on the same cellular connection at the same time.
Smart Device	A smart device is a cordless electronic device (unless charging), mobile (easily transportable), connected (via Wi-Fi, 3G, 4G, etc.) that can operate the Dexcom G5 Mobile App or the Dexcom Follow App. Examples of smart devices are smartphones or tablets. For a list of compatible smart devices, see dexcom.com/compatibility.
Standard Home Glucose Monitoring	Self-monitoring of BG using blood taken from the finger and a BG meter.
Trend Arrow	The arrow next to the Sharer's glucose value, located on the Sharer's profile on the Dexcom Follow App. This is the same trend arrow that is found on the Dexcom G5 Mobile Receiver.
Trend Graph	Displays the pattern of the Sharer's glucose information.

(Continued on next page)

(Continued from previous page)

Wi-Fi or Wireless Internet	A wireless technology that allows electronic devices access to the Internet. These networks can include your home Internet or one found at a public location.

20.2 Dexcom Share Overview

Dexcom Share is a feature within the Dexcom G5 Mobile App. It allows for remote monitoring from one person, the Sharer, of Dexcom G5 Mobile CGM data to another person, the Follower.

Dexcom Share includes:

- Dexcom G5 Mobile CGM System
- Sharer's smart device
- Dexcom G5 Mobile App
- Internet connection
- Follower's smart device
- Dexcom Follow App

You cannot use the Share feature with Dexcom G5 Mobile Receiver.

Once the Sharer activates the Share feature in their Dexcom G5 Mobile App, the smart device transfers sensor glucose readings to the Dexcom Share Cloud using either Wi-Fi or a cellular data plan. Then, the sensor glucose readings are sent from the Dexcom Share Cloud to the Follower's smart device using Wi-Fi or the Follower's cellular data plan.

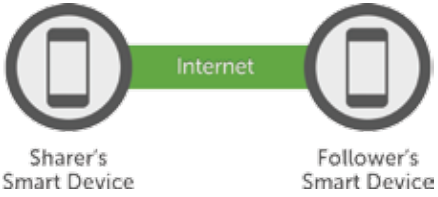


Figure 8. Sharing

The Sharer must be within 20 feet of their smart device in order to send data to their Follower or it will not work.

Dexcom Share Parts

	Sharer's smart device*[1]
	Follower's smart device*[1]
	Dexcom G5 Mobile App
	Dexcom Follow App
	Dexcom G5 Mobile Transmitter*
	Dexcom G5 Mobile/G4 PLATINUM Sensor*
	Internet/Wi-Fi or mobile data service/3G/4G/LTE*
	Bluetooth

**Must be purchased separately.*

[1]*A list of compatible devices can be found at dexcom.com/compatibility.*

Conditions Affecting Use

Once sharing is active, make sure the Share's and Follower's smart device settings are not altered.

Make sure the Sharer's and Follower's smart devices have:

- Enough battery power to maintain sharing
- Sharer's smart device has Internet connection
- Notifications turned on. If turned off, Follower won't receive any notifications
- Follower's smart device has an Internet connection

Dexcom recommends charging the smart device when sharing.

20.3 Risks and Benefits

Risks

Dexcom Share is a feature of the Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System. The main risks involved with using the feature Dexcom Share are based on misunderstanding its purpose.

Remember that the Dexcom Share in the Dexcom G5 Mobile CGM System is a secondary notification feature, not a real-time remote monitoring system.

With using the Dexcom Share feature, there are 3 distinct parts of glucose monitoring:

1. **Blood glucose meter** - use this to make any treatment decisions.
2. **Dexcom G5 Mobile CGM System** - use the Dexcom G5 Mobile CGM System to complement, but not replace, information obtained from the blood glucose meter. It detects glucose trends and tracks glucose patterns.
3. **Dexcom Share** - this is an optional add-on to the Dexcom G5 Mobile CGM System that can share glucose information and notifications with up to five (5) other people. Shared sensor glucose readings and information can add another level of awareness.

Using the wrong glucose information for treatment decisions could lead to low or high glucose. Blood glucose values from a blood glucose meter may differ from the information displayed on Dexcom Follow App. All treatment decisions should be made using a blood glucose value from your meter, not the glucose information displayed on the Dexcom Follow App.

Followers who are concerned by notifications on the Dexcom Follow App should contact the patients and remind them to check their blood glucose with a blood glucose meter

before driving a car or making any treatment decisions, such as taking insulin or eating fast-acting carbohydrates.

Sharers should not rely on Followers to notify them about low or high glucose.

Any problems with smart device(s), *Bluetooth*, wireless Internet connection, mobile data connection, Dexcom Share Cloud or not being in the communication range could cause data to not be shared with the Follower. In addition, if the Delay setting is too long, the Follower might not be aware of glucose level changes in a reasonable time. Therefore, the Dexcom Share feature should be used only to give a secondary level of awareness and should not be expected to always communicate and transfer sensor glucose readings and information.

Benefits

Patients usually respond when their continuous glucose monitoring (CGM) systems alert them.

However, experts advise that an additional CGM alert to another person may be helpful in increasing the detection of low glucose or high glucose values, especially at night. The Dexcom Share feature enables this additional awareness, even when the Sharer and Follower are not in the same place.

The Dexcom Share feature may provide improved quality of life and greater peace of mind to patients, their caregivers and their support team by allowing the Dexcom G5 Mobile Continuous Glucose Monitoring System Alerts, Alarms and trend graphs to be checked remotely.

20.4 Safety Statement

Intended Use

The purpose of Dexcom Share Direct Secondary Displays is to notify another person, the Follower, of the patient's Dexcom Continuous Glucose Monitoring (CGM) System sensor glucose information.

The Secondary Displays is intended for providing secondary notification of a continuous glucose monitoring system and does not replace real time continuous glucose monitoring (Dexcom G5 Mobile System) or standard home blood glucose monitoring. The Dexcom Share Direct Secondary Displays is not intended to modify or analyze data received from the continuous glucose monitor system. Nor is it intended to instruct, or to transmit information to the continuous glucose monitor system.

The Dexcom Share Direct Secondary Displays is not intended to serve as a replacement for a primary display device for a continuous glucose monitoring system. The Dexcom Share Direct Secondary Displays is not intended to receive information directly from the sensor or transmitter of a continuous glucose monitoring system.

Important User Information

Please review the indications, contraindications, warnings, precautions, cautions and other important information in the Dexcom G5 Mobile System User Guide. Dexcom Share is a feature of the Dexcom G5 Mobile System.

If you do not have the Dexcom G5 Mobile System User Guide, you can view it on dexcom.com or call **1.877.339.2664** to request a copy. Availability hours: Monday-Friday, 6am-6pm PST. Please contact your healthcare professional during hours the line is unavailable.

Contraindications

Do not bring the smart device (e.g., mobile phone, tablet computer) into a room containing medical equipment such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or diathermy.

These smart devices have not been tested with this equipment. Exposure to these types of equipment could heat and damage the smart devices so that they are unable to send or receive glucose information.

Warnings

Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.

This device is not intended to replace self-monitoring practices advised by a physician. Dexcom Share does not work alone. Dexcom Share does not replace the Dexcom G5 Mobile System and requires Share to be turned “On” to communicate glucose information to the Follower.

You cannot use Dexcom Share to make treatment decisions, such as how much insulin to take. Dexcom Share does not replace a blood glucose meter. Always use the values from a blood glucose meter for treatment decisions.

Blood glucose values may differ from the sensor glucose information. Using the sensor glucose information for treatment decisions could lead to low or high blood glucose values.

Precautions

Do not use Dexcom Share as the main source of CGM glucose trend information. Use the Dexcom G5 Mobile Receiver as the main device to track sensor glucose information, notifications and alarms.

At times, the patient will be unable to share data using Dexcom Share, and the Follower might miss helping the patient in the event of low or high blood glucose values. Do not rely solely on the Follower to alert the patient of low or high glucose events or other important information. At times, the Follower may not receive data, and the patient will not be notified of this fact.

When using Dexcom Share, make sure Share is turned "On." If not, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values. If the patient's smart device does not have a connection or loses the connection, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

Do not use Dexcom Share unless both the patient's and Follower's smart devices have active Internet connections in order to share data. If either the patient or the Follower does not have a connection, loses their connection, turns off the connection ("Airplane Mode") or if the smart device is in Do Not Disturb mode, the patient will be unable to share data and the Follower might miss helping the patient in the event of low or high blood glucose values. To check this, make sure that the Follower's smart device can receive text messages. Follow notifications and text messages work by a similar process.

Make sure the patient's and Follower's smart devices have charged batteries or are connected to electrical outlets. If the smart device shuts down due to low battery, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

If the patient's smart device is powered off or restarted, make sure the Dexcom G5 Mobile App is reopened after the smart device is turned back on in order to resume sharing. If the G5 Mobile App is not reopened, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

Do not turn off sounds in the Follower's smart device at any time that he or she wants Follow notifications to be heard. The smart device settings override the Dexcom Follow App, and all notifications will be silent even if the Follower has selected a Dexcom Follow App notification sound. If the smart device has a vibrate feature and vibrate is On, the Dexcom Follow App notifications will only vibrate.

Check the delay settings on the patient's smart device to make sure they are not too long. The Follower will not receive notifications until after the time period in the delay has passed, and the Follower might miss helping the patient in the event of low or high blood glucose values if the delay is too long.

The patient should not choose to "Not Share" with the Follower at any time when he or she wants the Follower to get notifications. During the time the patient chooses to "Not Share," the Follower will not receive notifications and might miss helping the patient in the event of low or high blood glucose values.

Check the Dexcom Follow App's trend graph if the Follower's smart device has been off or if there is no data connection (e.g., Internet/Wi-Fi or mobile data service/3G/4G/LTE is lost, connection is turned off in Airplane Mode, or smart device touch is placed in Do Not Disturb mode). When the smart device is turned back on, the Follower will only receive the most recent notification and might miss helping the patient in the event of prior low or high blood glucose values.

Sharers and Followers should check whether their cellular service carriers support voice and data at the same time (simultaneous voice and data). If their carriers do not support simultaneous voice and data, the Dexcom G5 Mobile App may not be able to share glucose readings and the Dexcom Follow App may not be able to receive notifications or glucose readings during phone calls. Dexcom Share will resume sharing after the phone call has ended, and the Follower will receive any waiting notifications after the phone call has ended.

20.5 Setting up Dexcom Share

Dexcom Share Description

What Dexcom Share does:

- Connects your smart device with your Follower's smart device via either a Wi-Fi or mobile data connection (connect to Wi-Fi through a secured network to maintain data security)
- Invites and sends Followers your setting recommendations
- Displays the status of your smart device, and the Dexcom Share Cloud
    - Confirms your sensor glucose readings are being shared with your Follower(s)

What Dexcom Share does not do:

- Let you know when the Follower is not receiving your sensor glucose readings and information

Tips

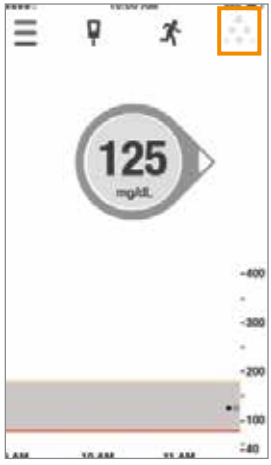
- Read the rest of the Dexcom G5 Mobile CGM System User Guide before using Dexcom Share
- Always confirm information with a BG meter before making treatment decisions
- Check the status screen after turning Dexcom Share “On” on the smart device to make sure it is working

Installing the Dexcom G5 Mobile App

Step	What you see	What you do
1		Download the Dexcom G5 Mobile App from your app store. See your smart device’s user manual for instructions. Download the Dexcom G5 Mobile App to use Dexcom Share.
2		Launch the Dexcom G5 Mobile App. Setup your smart device (see the Dexcom G5 Mobile User Guide) before sharing. Once your App has set up, activate Dexcom Share.

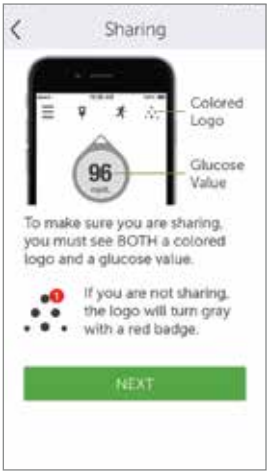
A series of screens walk you through Dexcom Share’s features highlighting important information.

Activating Your Share Feature

Step	What you see	What it means	What you do
1		Activates Dexcom Share. If Dexcom Share icon is gray, your Share feature has not been turned on.	**Tap** *Dexcom Share icon* in the upper right corner of your smart device's home screen.
2		Dexcom Share Welcome Screen.	**Read** screen. **Tap** *Next* when done.

(Continued on next page)

(Continued from previous page)

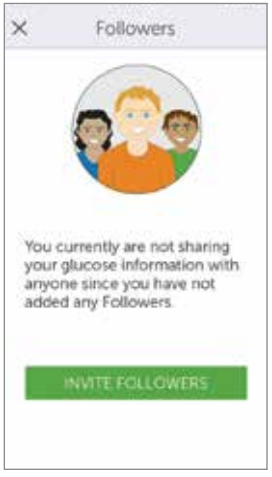
Step	What you see	What it means	What you do
3		Message about Internet access.	**Tap** *Next*.
4		How to know you are sharing your data.	**Tap** *Next*.

(Continued on next page)

(Continued from previous page)

Step	What you see	What it means	What you do
5		How to know your Follower is not getting your sensor data.	**Tap** *Let's Get Started* to move on and invite your Followers.

Inviting Followers

Step	What you see	What you do
1		**Tap** *Invite Followers* to set up your Followers.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
2	 	**Enter** the Follower's nickname and email address. **Confirm** Follower's email address. The Follower will get a Follow Invitation email. **Make sure** the Follower can access this email account from their smart device. **Tap** *Next*.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
3		**Tap** *Allow Trend Graph View's On/Off switch* if you want Follower to see your trend graph. **Tap** *Next*. Turned Off: Follower sees only your sensor glucose reading and trend arrow. Turned On: Follower sees your sensor glucose reading, trend arrow and trend graph.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
4		**Choose** if your Follower gets your urgent low, low and high sensor glucose Alarm/Alerts. **Choose** if you want your Follower to get prompts if they are not receiving your sensor glucose readings. **Select** what Alarms/Alerts your follower gets and how long you are low/high or not sharing data (for example, if you want your Follower to know when your glucose is above 200 mg/dL for more than 2 hours, you can set up in the Follower Settings Menu). **Tap** *Save* for each Follower Setting "Save." **Tap** *Next* when done.

(Continued on next page)

(Continued from previous page)

Step	What you see	What you do
5		Before Follower invitation is sent, **review** the Summary screen. **Tap** *Send Invitation*. After sending invitation, you cannot adjust the Follower's settings.
6		To add more Followers: **Tap** *Followers* tab on the Share Status screen. **Invite** up to a total of five (5) Followers.

20.6 Using Dexcom Share

Dexcom Share Status

You can look at the Dexcom Share icon on your home screen to see if Dexcom Share is working. After turning Dexcom Share on, check its status.

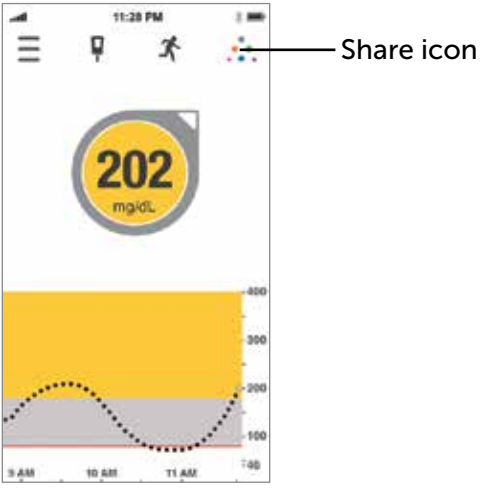


Figure 9. Dexcom G5 Mobile App Home Screen

Dexcom Share Status Icons

Status Tab	What it is
	The Share icon is in color when Dexcom Share is sending sensor glucose readings and information.
	The Share icon is gray with a red circle when Dexcom Share is not working. The sharer should tap on the grayed out Share icon when it is not working to get further information about the error.

(Continued on next page)

(Continued from previous page)

Status Tab	What it is
	The Share icon is light gray when Dexcom Share has not been activated. The sharer should tap the light gray icon to get started using Dexcom Share.

When a device or connection is not working, Dexcom Share will not work. The Sharer will not be able to send their sensor glucose readings and data to their Follower.

Troubleshooting Status Issues

Dexcom Share's status bar is a useful tool. It can help identify if there is a problem and Dexcom Share is not working. The following table provides troubleshooting tips for the Share status bar.

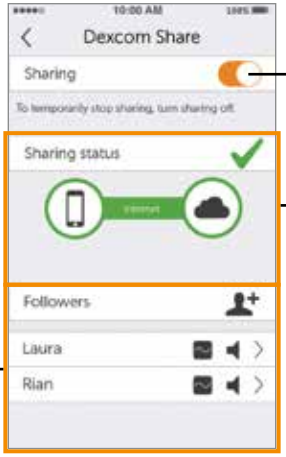

10:00 AM
Dexcom Share
Sharing
To temporarily stop sharing, turn sharing off.
Sharing status
Followers
Laura
Rian
On/Off Switch - Turns sharing on or off
Sharing Status Bar - Status of sharing your sensor glucose readings with your Followers
Follower List - Add Followers and lists status of Followers.

Figure 10. Dexcom Share Screen

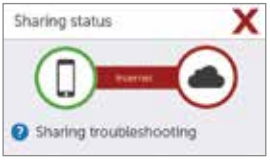
NOTE: Whether or not Dexcom Share is working and the Followers are receiving glucose Alarm/Alerts, you must always refer to your Dexcom G5 Mobile display device for your sensor glucose readings and alerts.

All treatment decisions must be based on your BG value from your BG meter.

What you see	What it means	What you do
	Green Check: All connections are working	N/A.
	Issue with: • Sharer's CGM data • Your smart device	The Sharer should make sure: • There is a glucose value on the smart device • Transmitter is in range of the smart device • Tap on blue "?" to learn more about how to troubleshoot this issue • The Sharer should allow up to 10 minutes for their status to turn green and a green check mark to appear If the Sharer continues to see this, the Sharer should turn off Share and then turn it back on.

(Continued on next page)

(Continued from previous page)

What you see	What it means	What you do
	Issue with: • Sharer's Internet connection • Dexcom Share Cloud	The Sharer should make sure: • Their Wi-Fi or cellular connection is ON • They are in an area that has cellular reception • They are not on a voice call • They can access the web via a browser • Check later or follow up with their Internet connectivity provider • **Tap** on blue "*?*" to learn more about how to troubleshoot this issue

Follower List

The Followers list allows the Sharer to manage their Followers.

In the Follower list you can:

- Invite a new Follower
- See the status of Followers you have invited
- Glance at what options your current Followers have

Icon/Status

What you see	What it means
	Invite a new Follower.

(Continued on next page)

(Continued from previous page)

What you see	What it means
	Follower is set to get prompts from their Sharer.
	Follower is able to view their Sharer's trend graph.
	Follower did not accept their Sharer's Follow Invitation email within 7 days. The Sharer can invite their Follower again by pressing on the + icon in the top right corner of the screen.
	Follower has been sent a Follow Invitation email but has not accepted it yet.
	Sharer stopped sharing with Follower. Follower will not get any of the Sharer's glucose information, Alarm/Alerts, or trend graph updates.

Editing/Removing Followers

Tap on a Follower to edit the Follower's profile (nickname or ability to view trend graph) or remove a follower. Remove a follower by tapping "Remove Follower." Once removed, they won't get glucose information or Alarm/Alerts.

NOTE: The Sharer cannot change any Follower settings after the Follow Invitation email is sent.

Stop Sharing

The Sharer can swipe the On/Off switch to temporarily stop glucose information and Alarm/Alerts from being sent to Followers. Sharing stops until the Sharer turns the On/Off Switch back on.

For reasons of safety and intended use, the Follower will get a message telling them their Sharer's data was set to *Not Sharing*. The Follower's dashboard will show the Sharer has stopped sharing glucose information.

20.7 Dexcom Follow App

Dexcom Follow App Description

The Dexcom Follow App is a separate App from the Dexcom G5 Mobile App. Your Followers only need to download and install the Dexcom Follow App.

What the Dexcom Follow App does:

- Allows Follower to view the Sharer's glucose information
- Allows Follower to get Alerts and Alarms
- Allows the Follower to view the Sharer's trend graph

What the Follower app does not do:

- Provide treatment advice
- Interact with the Dexcom G5 Mobile App

Receiving Dexcom Follow Invitation Email

After getting the Sharer's Follow invitation by email, the Follower sets up their smart device.

Glucose Alarm and Alerts

A glucose prompt is a visual message saying "Glucose notification from [Sharer's name]" that appears on the screen of the Follower's smart device. The prompt may include sounds, depending on their smart devices settings.

Types of prompts your Followers get:

- Low Sensor Glucose Reading
- Urgent Low Sensor Glucose Reading (< 55 mg/dL)
- High Sensor Glucose Reading

Your Follower can change some of the initial settings to fit their needs. The Follower cannot change your permission settings to see your Trend Graph.

Sharer Status Changes That Notify the Follower

Some Sharer status changes will prompt your Followers.

- **Not Sharing** - Sharer decides to temporarily stop sharing
- **Removed by Sharer** - Sharer removes Follower
- **No More Data** - Prompt Sent when active glucose sharing is stopped for any reason, other than the Sharer turning Share "Off"
    - The Follower should contact the Sharer for more information about the data interruption

The Follower Dashboard

Figure 11. Follower Dashboard

If you don't allow your Follower to see your Trend Graph, they will only see your glucose reading and trend arrow.

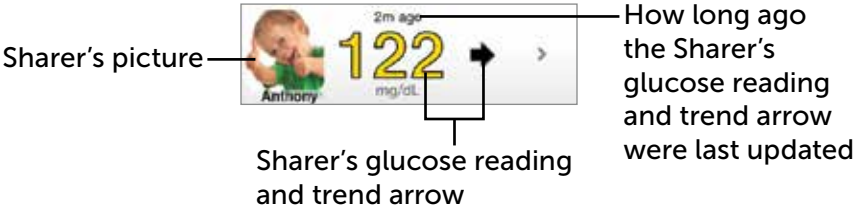


Figure 12. Follower Information

If you choose to have your Follower see your Trend Graph, they see:

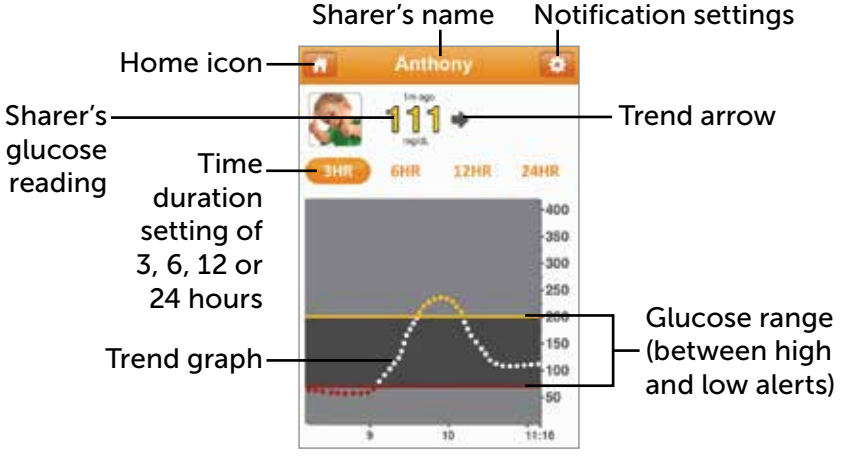


Figure 13. Follower Information With Trend Graph

20.8 Troubleshooting

Dexcom Share Troubleshooting

Troubleshooting Status - See the Troubleshooting Status Issues portion of Section 20.6.

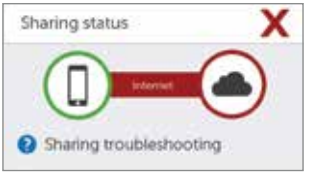


Figure 14. Sharing Status Troubleshooting

Sharing Checklist

To share, you need to:
Make sure your smart device works with the Dexcom G5 Mobile App. To see a list of supported smart devices and operating systems, go to: dexcom.com/compatibility

- The Dexcom G5 Mobile App is open or running in the background
- Smart device has an active Internet connection (Wi-Fi, 3G, 4G, LTE). The Sharer can check to see if the Internet connection is working by trying to open a web page on the Sharer's smart device
- If on a phone call using your smart device, your CGM information may not upload into the Share Cloud while on your call
- Airplane Mode turned off
- Do Not Disturb is turned off
- Smart device sound is on in order to hear prompts
- Smart device is sufficiently charged or charging
- Smart device is within 20 feet of the transmitter
- Smart device has 35 MB of available memory
- Refer to the smart device user manual for further instructions

Tips

- Read the Dexcom G5 Mobile CGM System User Guide before using the Dexcom Share feature
- Always confirm information with a BG meter before you make treatment decisions

Page intentionally left blank

Index

A

Alarm, 175
  App Recommended Settings, 183
  Clearing, 188
  Prompts, 178
  Receiver Beeps and Vibrations, 184
  What is an, 176
Alarm and Alerts
  Changing Receiver, 204
  Customizing, 195
Alerts, 175
  Clearing, 188
  Default, 176
  Low Repeat/High Repeat, 185
  Low/High Glucose, 179,180
  Main Menu, 207
  Receiver
    Default Beep and Vibrations, 184
  Rise Rate/Fall Rate, 181, 182
  Rise Rate/Fall Rate/Repeat/Signal Loss, 177
  What are, 176

C

Calibration, 92
  Entering into app, 101
  Entering into your receiver, 104
  Errors, 106
  Preparing for, 100
  Prompts, 96, 98, 99
  What is it, 92
  When to Calibrate, 95
  Why is Calibrating important, 92
CGM System
  Basic Maintenance, 222
  Different Monitoring Methods, 50
  Disposal, 228
  Overview, 42
  Storage, 226

E

Error Messages, 146
Event
  Categories, 154
  Definition, 153
Events, 153
  Entering
    App, 162
    Receiver, 168
  Viewing, 170

G

Glucose Information
  Rate of Change Arrows, 145
  Trend Screen, 138, 144

R

Rate of Change Arrows, 139, 144, 145
Receiver
  Home Screen, 141
  Initial set up, 64
    Overview, 45

S

Safety Statement
  Contraindications, 19
  Indications, 18
  Precautions, 21, 23, 24, 25, 27
  Warnings, 20, 21, 22, 24, 26
Sensor Insertion
  Choosing site, 75
Sensor Session
  Attaching transmitter, 80
  Definition, 8
  Ending, 110
  Ending Early

App, 119
Receiver, 121
Ending Seven Day, 111
Inserting sensor, 76
Prepping for Sensor Insertion, 72
Preventing Sensor Failures, 123
Receiver: Starting a Session, 84
Remove Sensor Pod and Transmitter, 124
Starting a, 69
Starting with app, 83
Sensor Session Warmup
Warmup, 90
Signal Loss Alert
Signal Loss, 183, 187, 208
Sound/Vibration Prompts, 116
System Components, 39

T

Technical Information, 237
Transmitter
Attaching, 80
Battery Messages, 127
Connecting/Pairing Transmitter with App, 58
Connecting/Pairing with Receiver, 66
End of Transmitter Battery, 127
Overview, 44
Remove from Sensor Pod, 124
Safety Statements, 24
Troubleshooting, 287

W

Warranty, 215

Notes

Dexcom®

© 2015 Dexcom, Inc. All rights reserved.

Covered by patents www.dexcom.com/patents.

Dexcom, Dexcom Follow, Dexcom G4, Dexcom G4 PLATINUM, Dexcom G5, Dexcom G5 Mobile, Dexcom Share, Follow Dashboard, and G5 are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. All other product or company names that may be mentioned in this publication are tradenames, trademarks or registered trademarks of their respective owners.

Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121 USA

Phone: **1.858.200.0200**
Tech Support: **1.877.339.2664**
Web: dexcom.com

LBL012787 Rev 005 MT22864